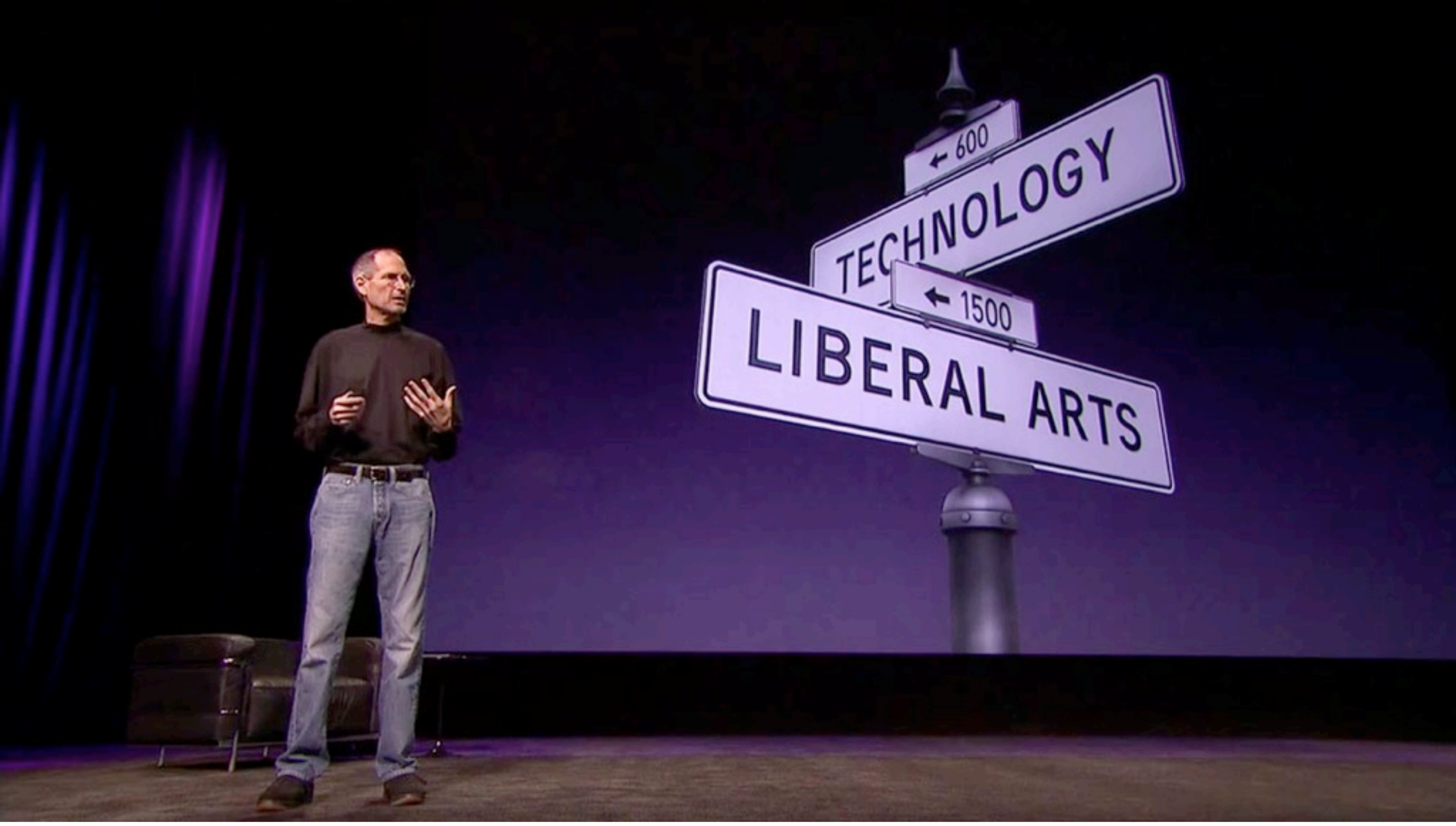
Health-IT 컨버전스로 인한 파괴적 의료 혁신

: 유전자에서, 인공지능, 3D 프린터, 웨어러블까지

성균관대학교 휴먼ICT융합학부 교수
Health-IT Convergence Evangelist
최윤섭, Ph.D.



"It's in Apple's DNA that technology alone is not enough.
It's **technology** married with **liberal arts.**"

The Convergence of IT, BT and Medicine

최윤섭의 Healthcare Innovation

헬스케어, 바이오테크놀러지, 신약개발, IT & 헬스케어 컨버전스, 기업가정신

스티브 잡스가 맞춤 의료에 남기고 간 것들

IT 혁명을 통해 세상을 바꿔 놓았던 스티브 잡스. 그가 '맞춤 의료 (personalized medicine)' 에 남겨 놓은 것이라니, 많은 분들이 의아해 할지도 모릅니다. 스티브 잡스는 그의 지병이었던 췌장암의 재발로 투병하다가 2011년 10월 유명을 달리하면서 많은 사람들을 안타깝게

RECENT POSTS

스티브 잡스가 맞춤 의료에 남기고 간 것들

Posted On November 24, 2013 | 2 Comments

IT 혁명을 통해 세상을 바꿔 놓았던 스티브 잡스. 그가 '맞춤 의료 (personalized medicine)' 에 남겨 놓은 것이라니, 많은 분들이 의아해 할지도 모릅니다. 스티브 잡스는 그의 지병이었던 췌장암의 재발로 투병하다가 2011년 10월 유명을 달리하면서 많은 사람들을 안타깝게 [...]

한국경제신문에 제 블로그가 소개되었습니다!

November 1, 2013 | 0 Comments

FDA, 드디어 헬스케어 앱에 대한 최종 가이드라인을 내어놓다

October 27, 2013 | 2 Comments

구글 글래스, 의료의 미래를 바꿀 것인가? (2): 수술에 구글 글래스를 활용한 의사들

October 6, 2013 | 0 Comments

구글 글래스, 의료의 미래를 바꿀 것인가? (1)

September 24, 2013 | 1 Comments

바이오테크놀러지, 헬스케어, 신약개발, 디지털/스마트 헬스케어, Personalized Medicine, IT-헬스케어의 융합, 기업가 정신 등의 이슈 및 트렌드를 follow-up 하고 공부하기 위한 블로그입니다.

RECENT POSTS

스티브 잡스가 맞춤 의료에 남기고 간 것들

November 24, 2013

한국경제신문에 제 블로그가 소개되었습니다!

DIGITAL HEALTHCARE

한국경제신문에 제 블로그가 소개되었습니다!

Posted On November 1, 2013 | 0 Comments

Healthcare Innovation

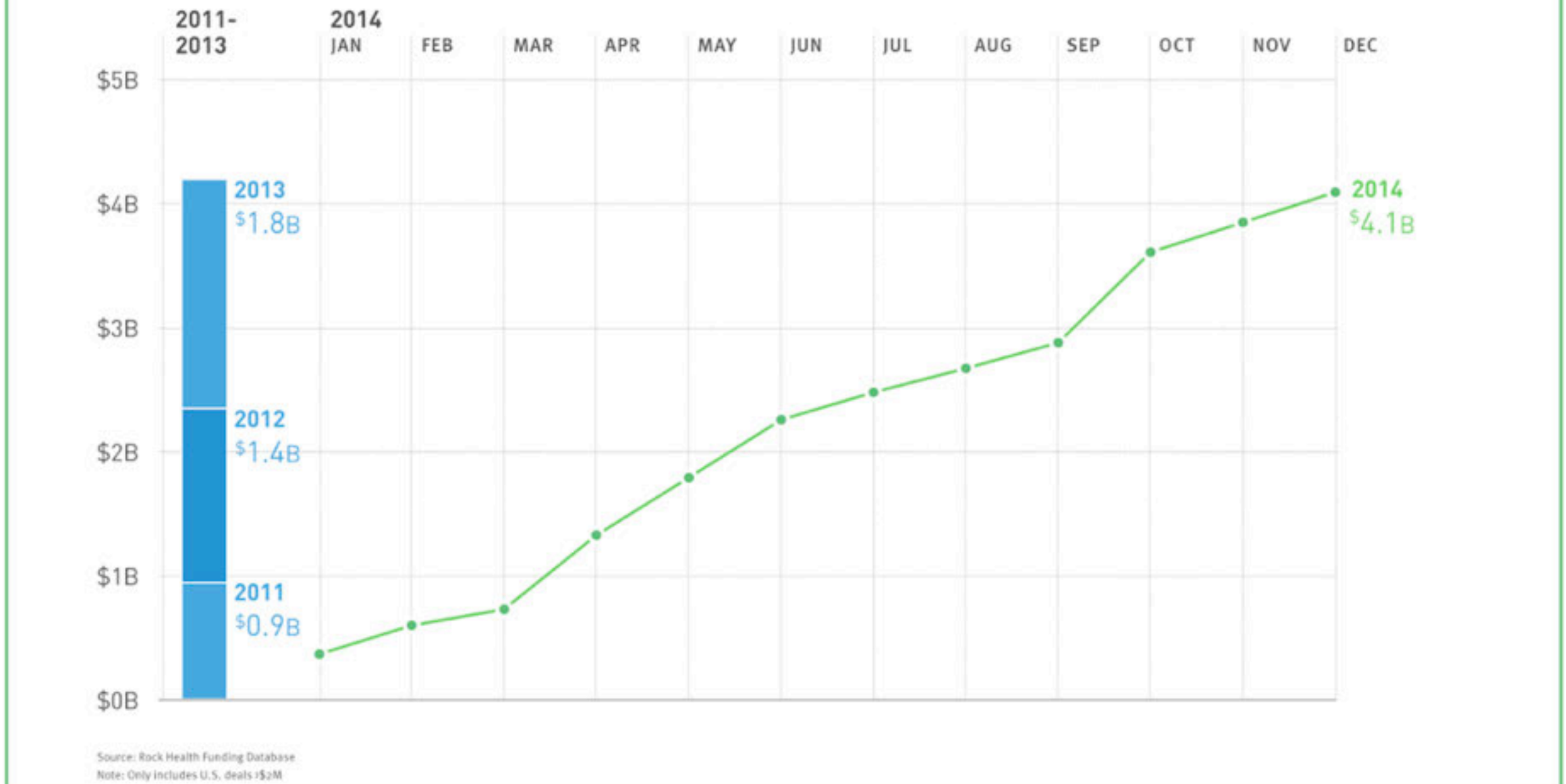
이 미 시 작 된 미 래
헬스케어 이노베이션

최 윤 섭 지 음

클라우드나인
CLOUD 9


CHANGE
AHEAD

Inevitable Tsunami of Change



- 2014 디지털 헬스케어 스타트업의 총 펀딩 규모는 **$4.1 billion**
- 이는 **2011-2013**년의 펀딩 규모를 모두 합친 것보다도 더 큰 규모
- **2013**년에 비해서는 **125%** 증가한 규모

http://rockhealth.com/2015/01/digital-health-funding-tops-4-1b-2014-year-review/

Health 2.0 Seoul Chapter's First Event

한국에서도 고조되는 Health 2.0 에 대한 관심

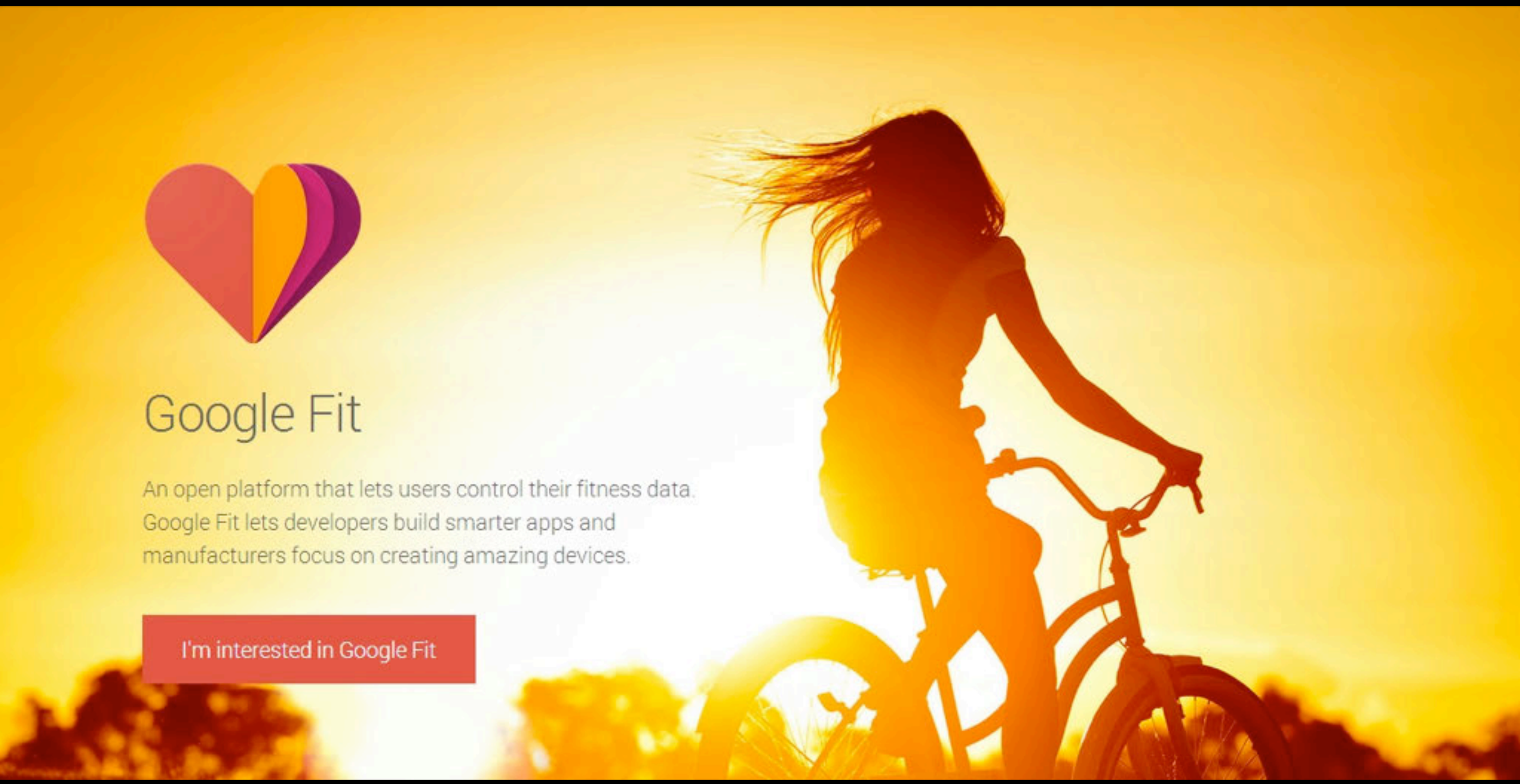
3월 24일 (일) 아침 9시, Health 2.0 Seoul Chapter

의사, IT 벤처 기업, 대기업, 교수, 벤처캐피털리스트 ... etc

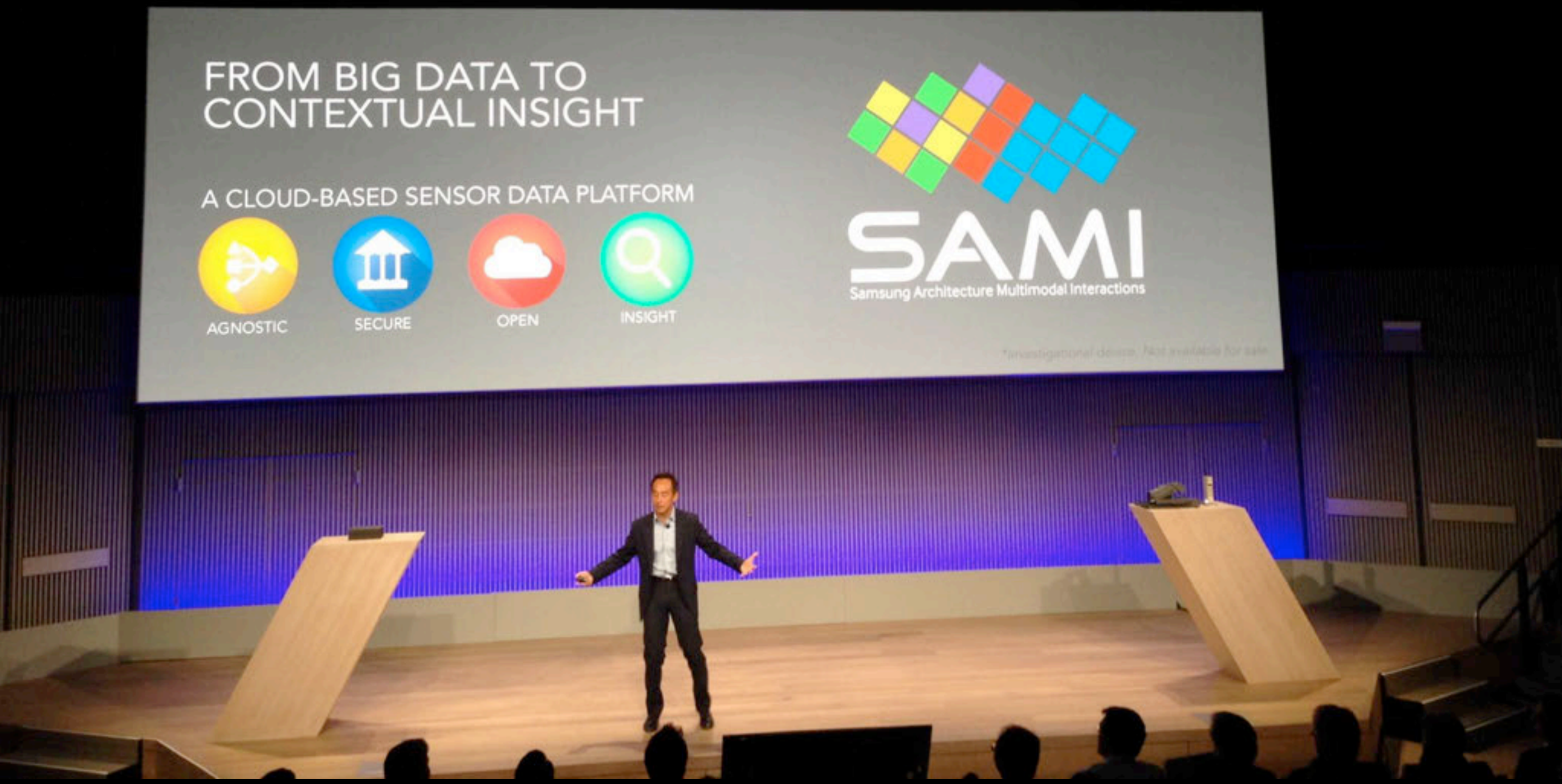
변화에 대처하기 위한 출발점은?


9:41 AM
100%
Dashboard
Calories Burned
Daily Avg: 428
467cal
Today
743
136
May 5
12
19
26
June 2
Sleep
Daily Avg: 7h 9m
7h 29m
Last Night
9.5
9:41 AM
100%
Calories Burned
467cal
Today
743
136
12
19
26
June 2
All Data
Data Point

Google Fit


Google Fit
An open platform that lets users control their fitness data. Google Fit lets developers build smarter apps and manufacturers focus on creating amazing devices.
I'm interested in Google Fit

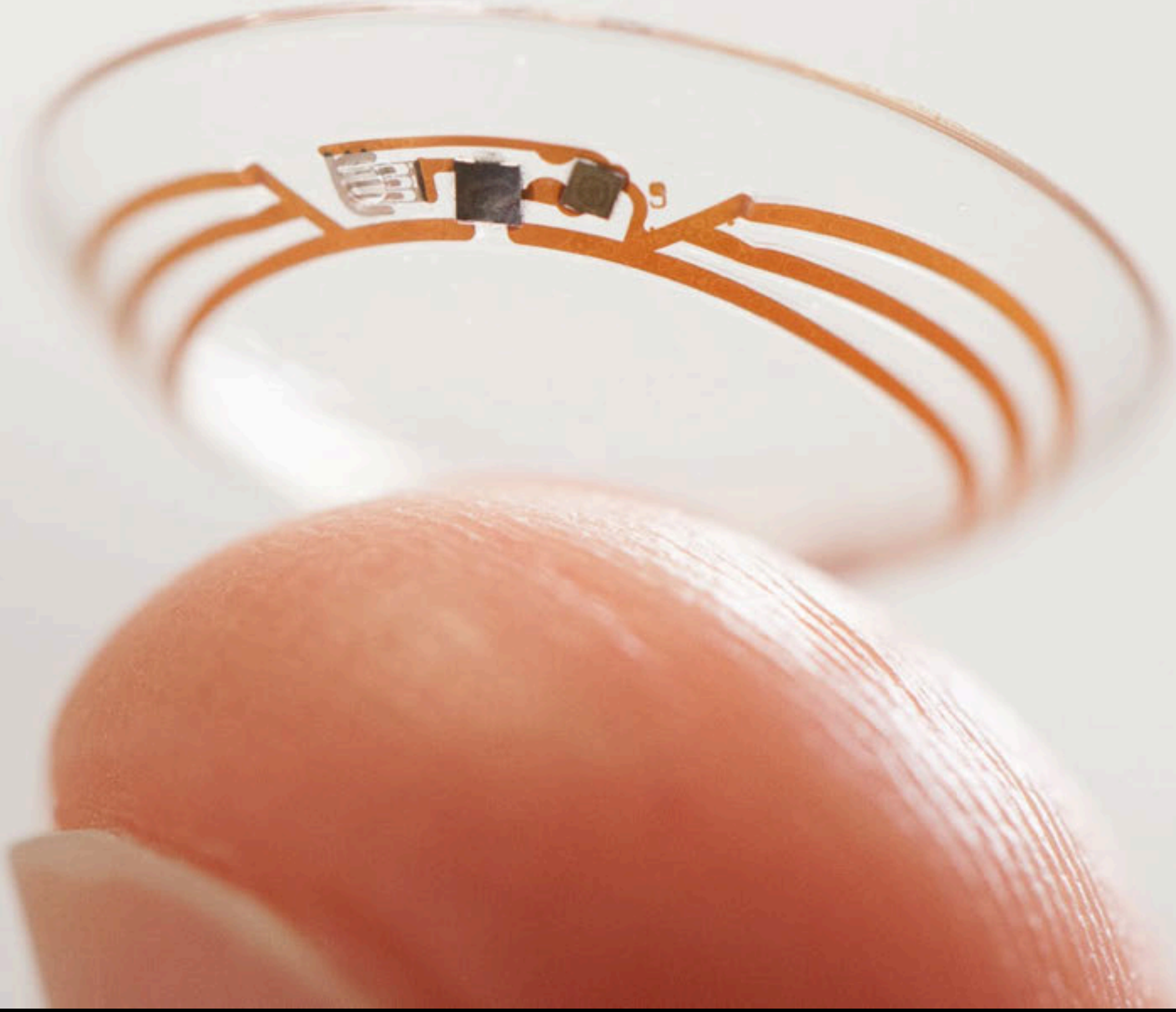
Samsung SAMI

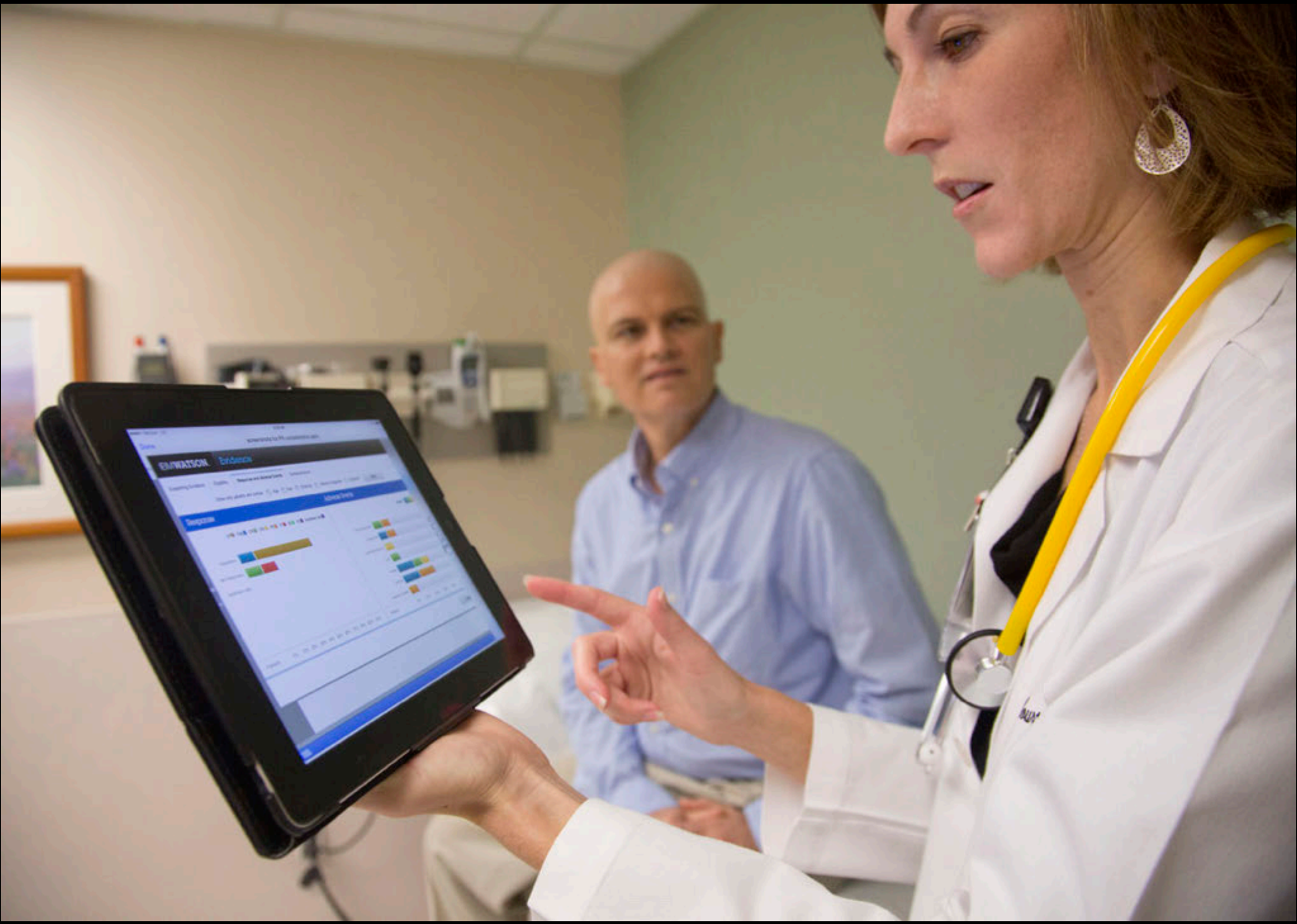


Apple Watch


60
95
30
ANGELICA


Kimberly-Clark




IBM WATSON
Diagnosis

QUALCOMM TRICORDER XPRIZE®

TURNING SCIENCE FICTION INTO SCIENCE REALITY

THE $10 MILLION GLOBAL COMPETITION TO PUT HEALTHCARE IN THE PALM OF YOUR HAND

LEARN MORE ›

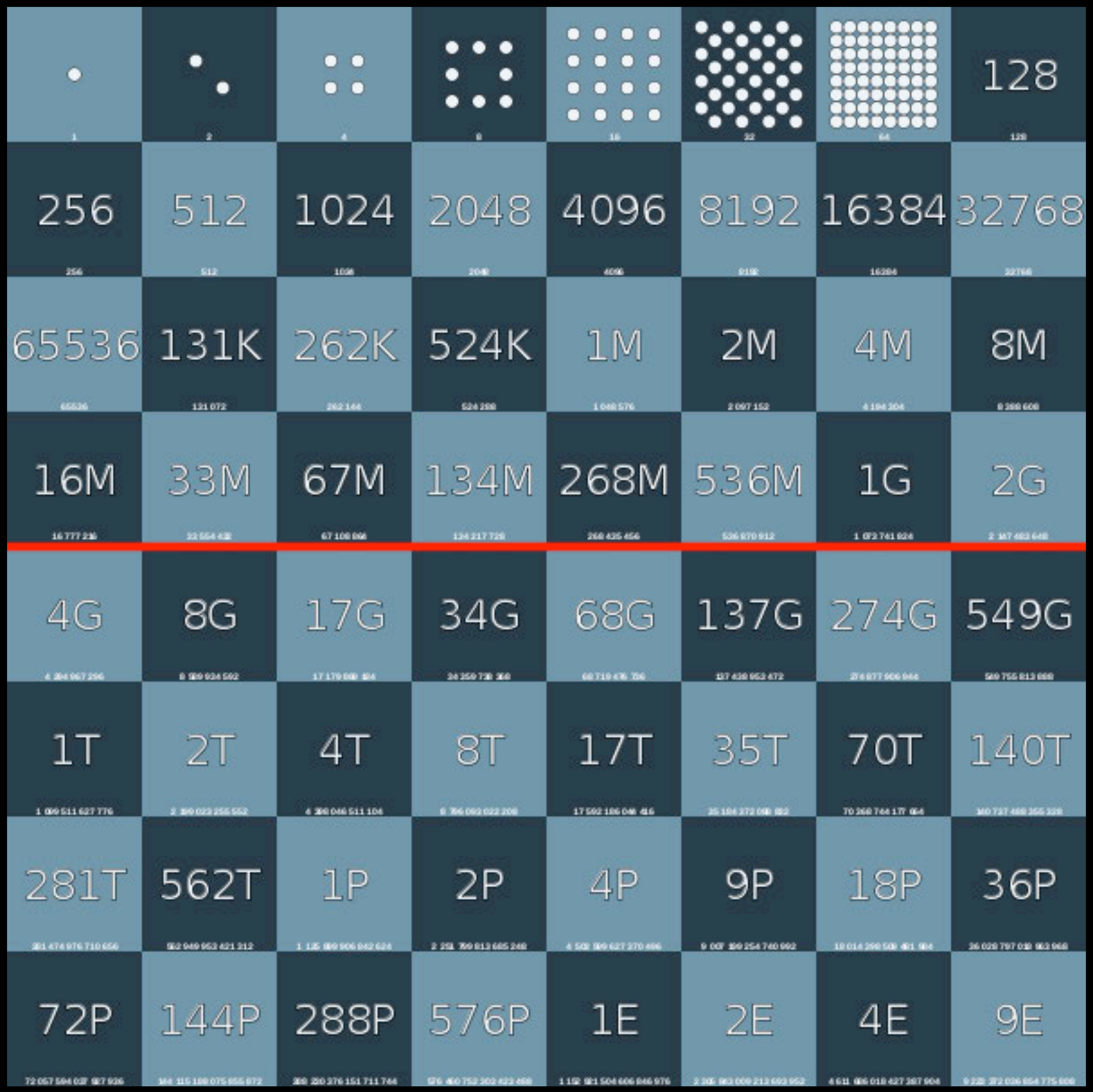
A $10 MILLION COMPETITION TO BRING HEALTHCARE TO THE

PALM OF YOUR HAND

Imagine a portable, wireless device in the palm of your hand that monitors and diagnoses your health conditions. That's the technology envisioned by this competition, and it will allow unprecedented access to personal health metrics. The end result: Radical innovation in healthcare that will give individuals far greater choices in when, where, and how they receive care.

LEARN MORE ABOUT THE COMPETITION ›

Why Now?



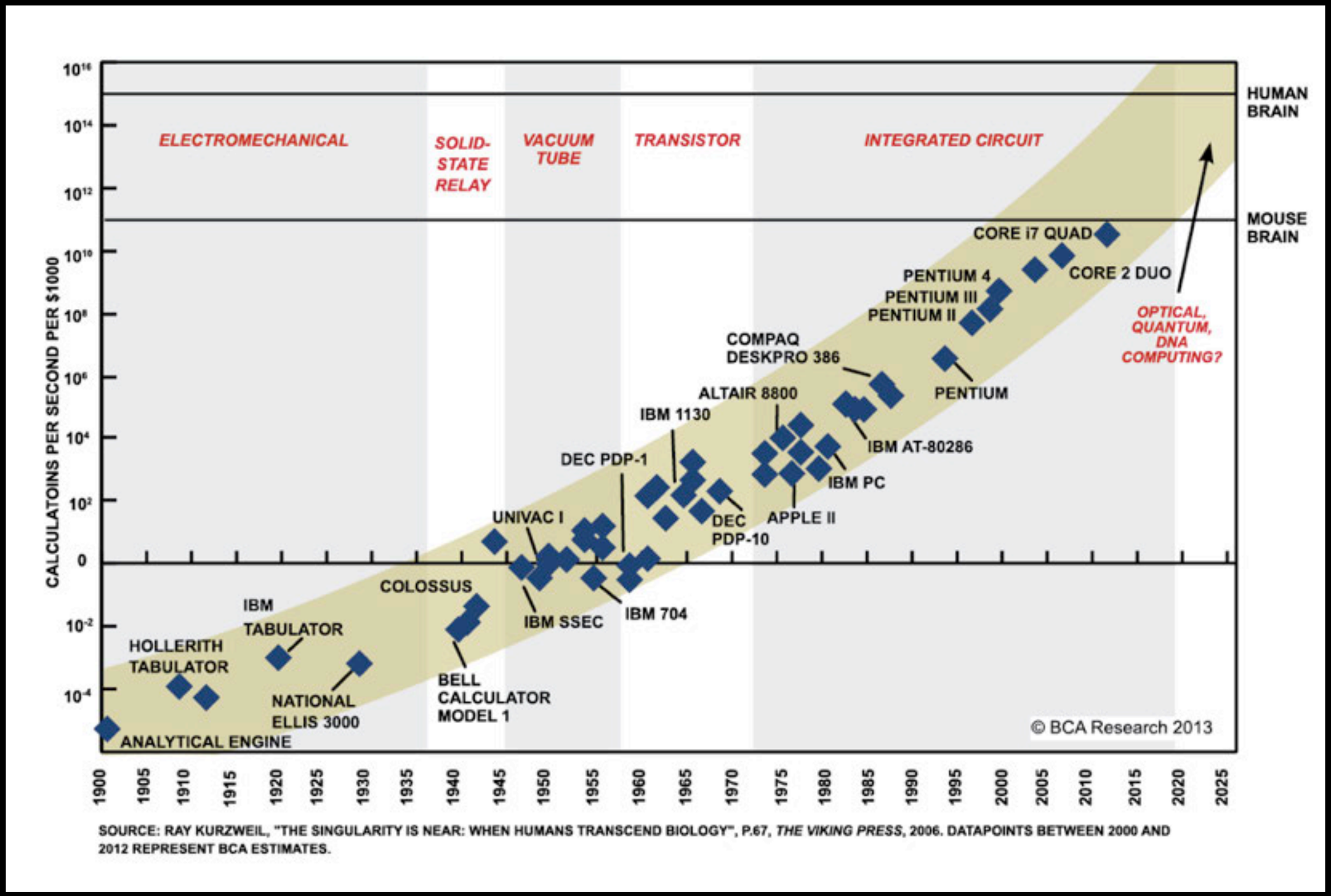
9,223,372,036,854,775,808

Moore's Law

"The number of transistors in a dense integrated circuit doubles approximately every two years."

- Microprocessor price
- Memory capacity
- The number of pixels in digital camera

Moore's Law



SOURCE: RAY KURZWEIL, "THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY", P.67, *THE VIKING PRESS*, 2006. DATAPOINTS BETWEEN 2000 AND 2012 REPRESENT BCA ESTIMATES.

"2006년이 무어의 법칙에 따라 2배씩 증가한,
32번째 되는 해가 된다!
우리는 이미 체스판의 후반부에 접어들었다."

ASCI RED (1997)

WORLD'S 1ST TERAFLOPS MOBILE PROCESSOR

Playstation 3 (2006)

CRAY-2 (1985)

iPad2 (2011)


iPad 3G
9:41 AM
Thursday
27
Calendar
Contacts
Notes
Maps
Videos
YouTube
iTunes
App Store
Game Center
FaceTime
Camera
Photo Booth
Settings
Safari
Mail
Photos
iPod

- Personal Genome Service
  - 23andMe
- Diagnosis by Computers
  - IBM Watson
- Wearable Healthcare Devices
  - Google Glass
  - Proteus Digital Health
- 3D Printers
- Smart/Mobile Healthcare
  - AliveCor
  - Apple HealthKit

Personal Genome Service

개인 유전정보 분석

Human Genome Project

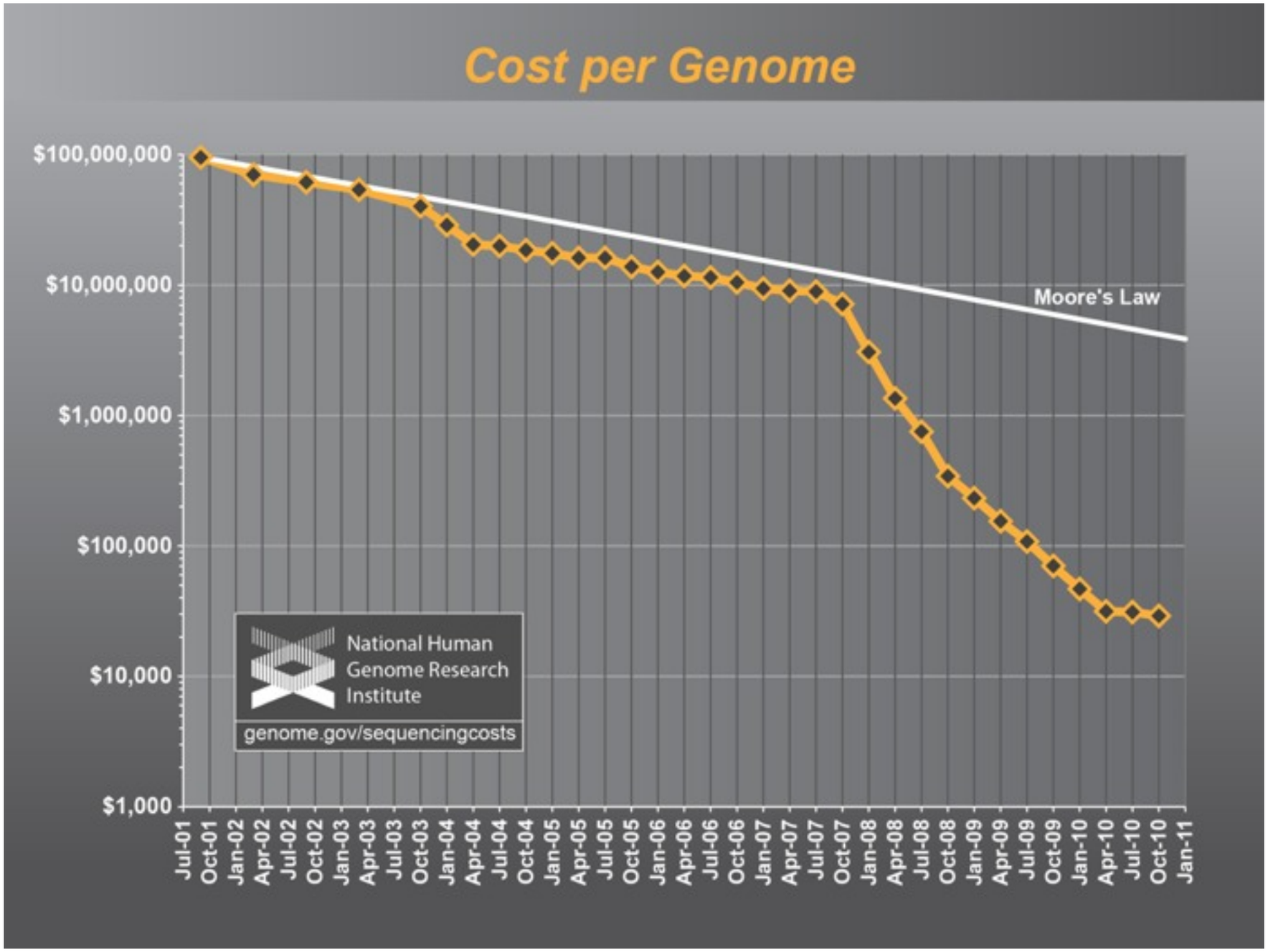
Impacting many disciplines

Courtesy
U.S. Department of Energy
Human Genome Program

Global Carbon Cycles
Industrial Resources • Bioremediation
Evolutionary Biology • Biofuels • Agriculture • Forensics
Molecular and Nuclear Medicine • Health Risks

YGA 99-1133R

What have been changed?



2003	Human Genome Project	13 years (676 weeks)	$2,700,000,000
2007	Dr. Craig Venter's genome	4 years (208 weeks)	$100,000,000
2008	Dr. James Watson's genome	4 months (16 weeks)	$1,000,000
2009	(Nature Biotechnology)	4 weeks	$48,000
현재		1-2 weeks	~$5,000

Over the last decade,

13 years ⟶ 1 week

(676 weeks)

Over the last decade,

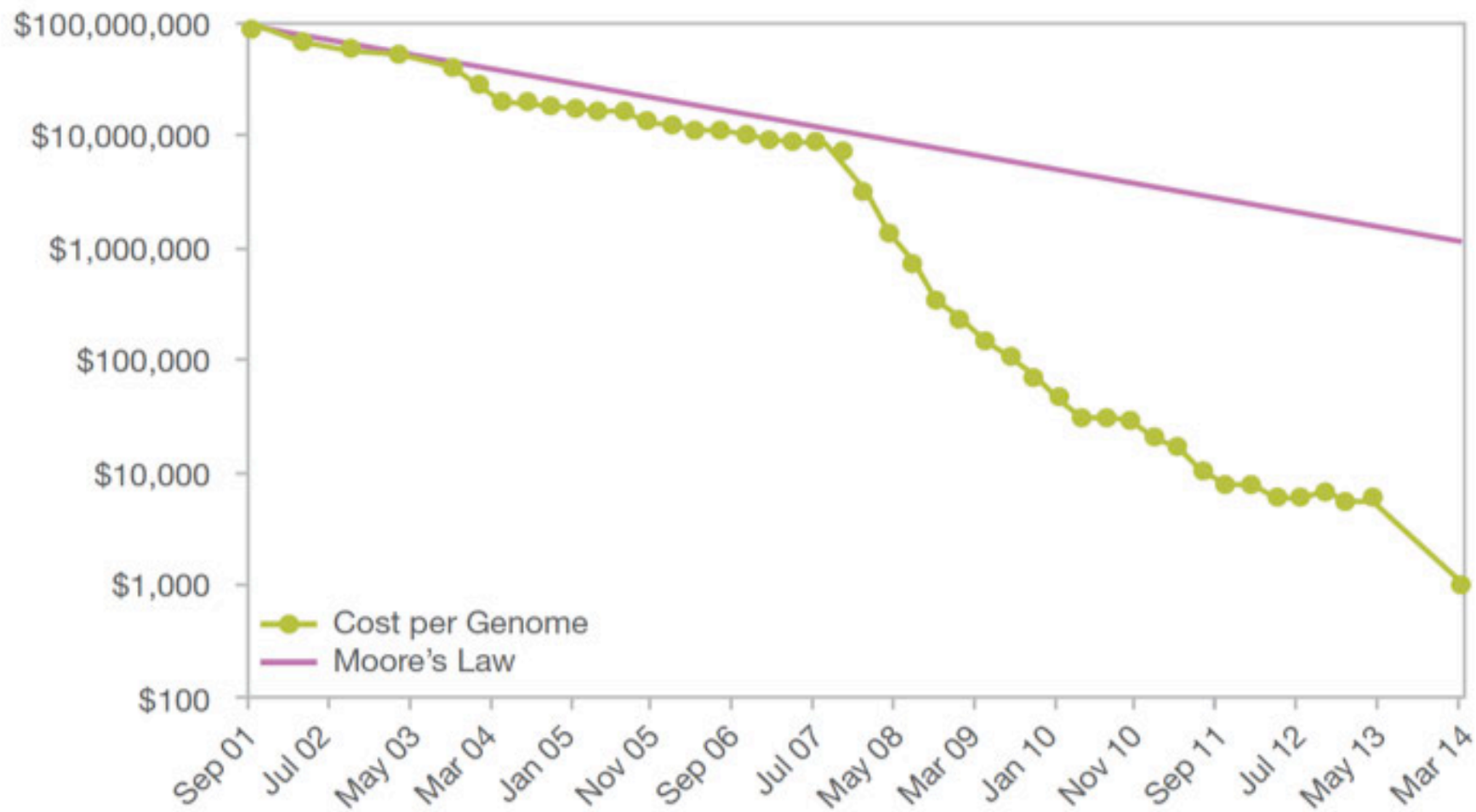
$2,700,000,000 ⟶ ~$5,000

Ferrari 458 Spider

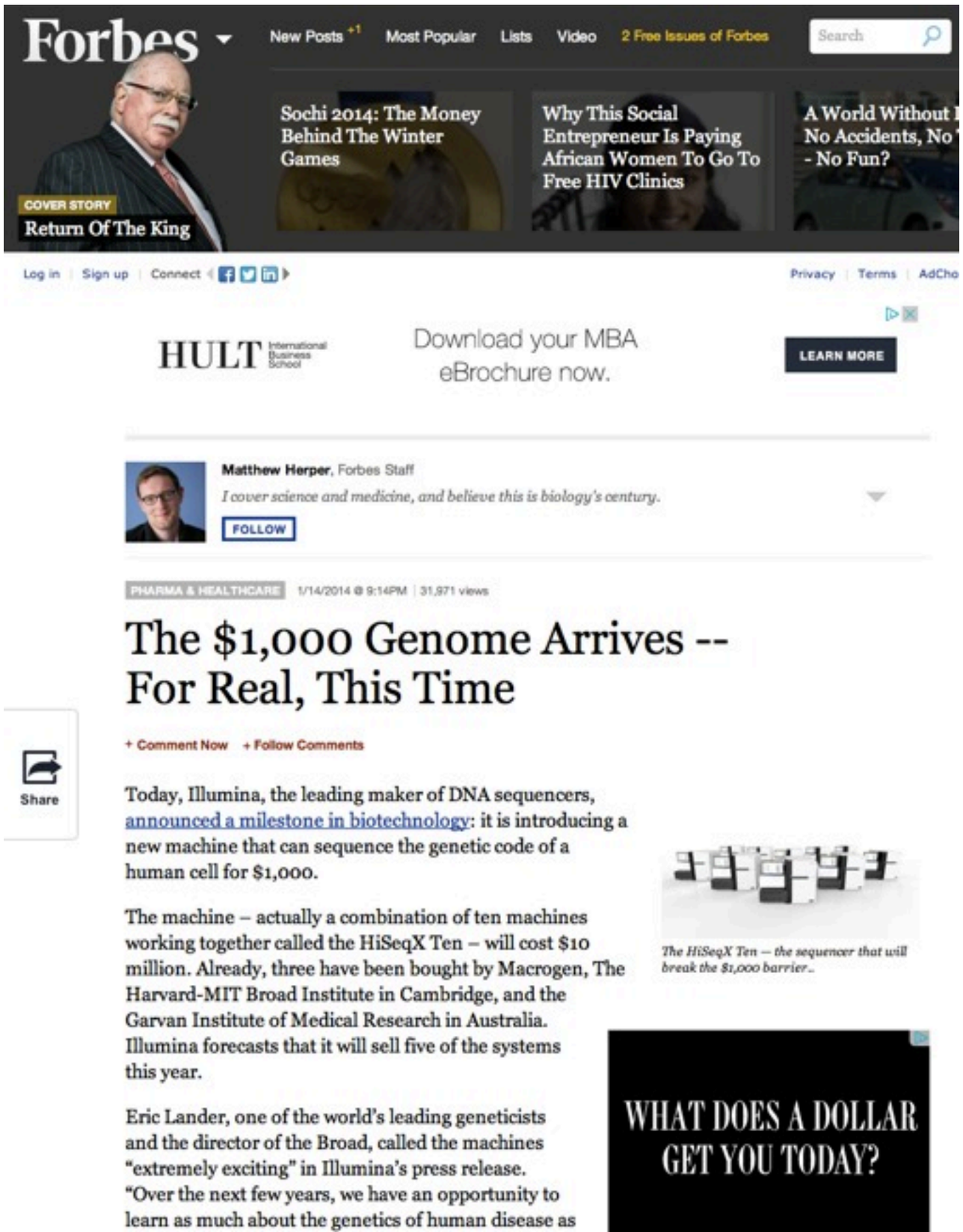
$398,000 ⟶ 40 cents

http://www.guardian.co.uk/science/2013/jun/08/genome-sequenced

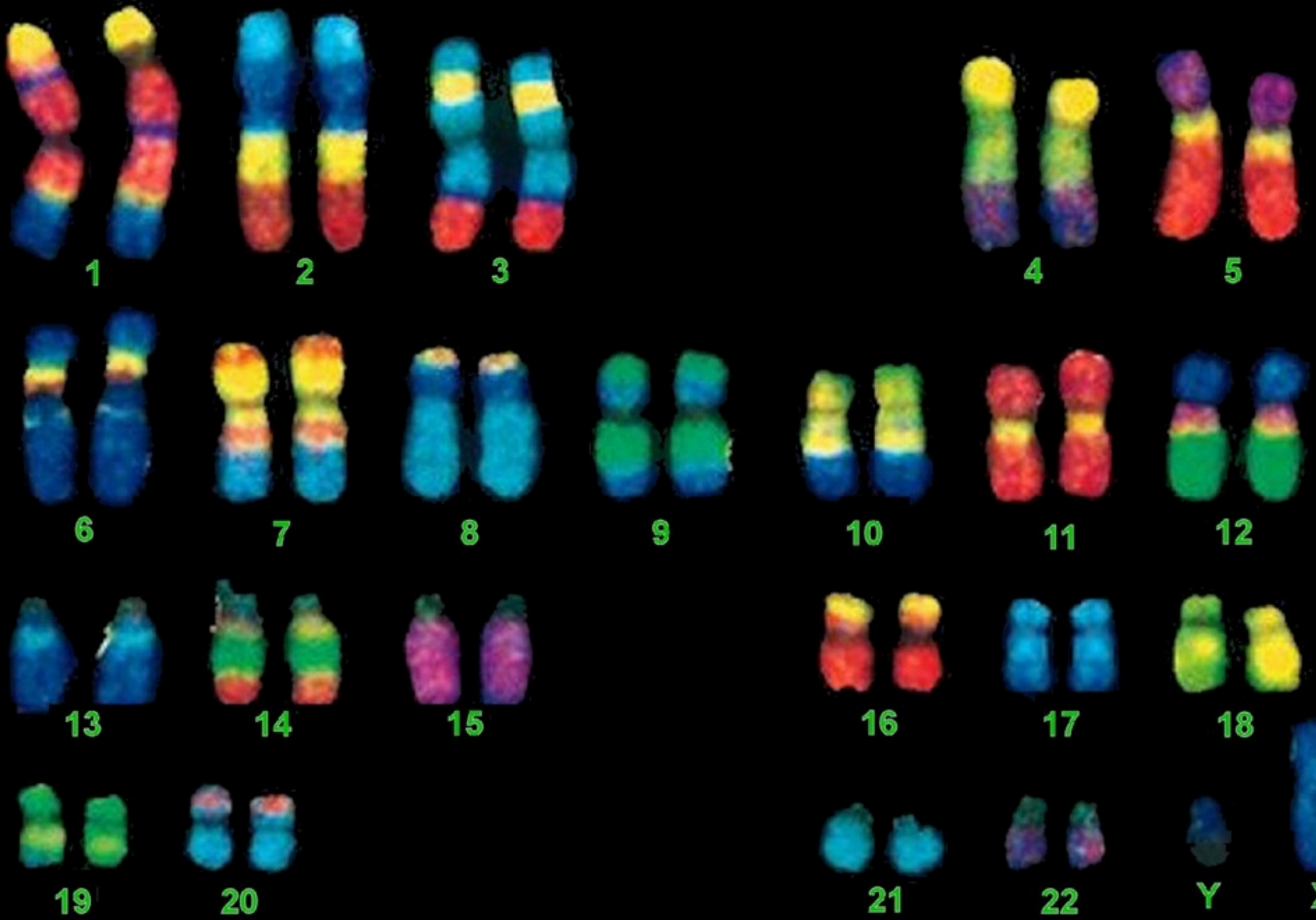
The $1000 Genome is Already Here!



The $1000 Genome is Already Here!




23andMe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“THE MOST DARING CEO”

CEO/Co-Founder Anne Wojcicki

- Sergey Brin donated $50m to fund the 23andMe's Parkinson's Disease research, when the company revealed that he's high-risk for the condition.

- Sergey Brin and his mother, who is a Parkinson's Disease patient, turned out to have same mutation on LRRK2 gene.

DTC Genetic Testing

Direct-To-Consumer

A little spit is all it takes!

Results within 6-8 weeks

120 Disease Risk

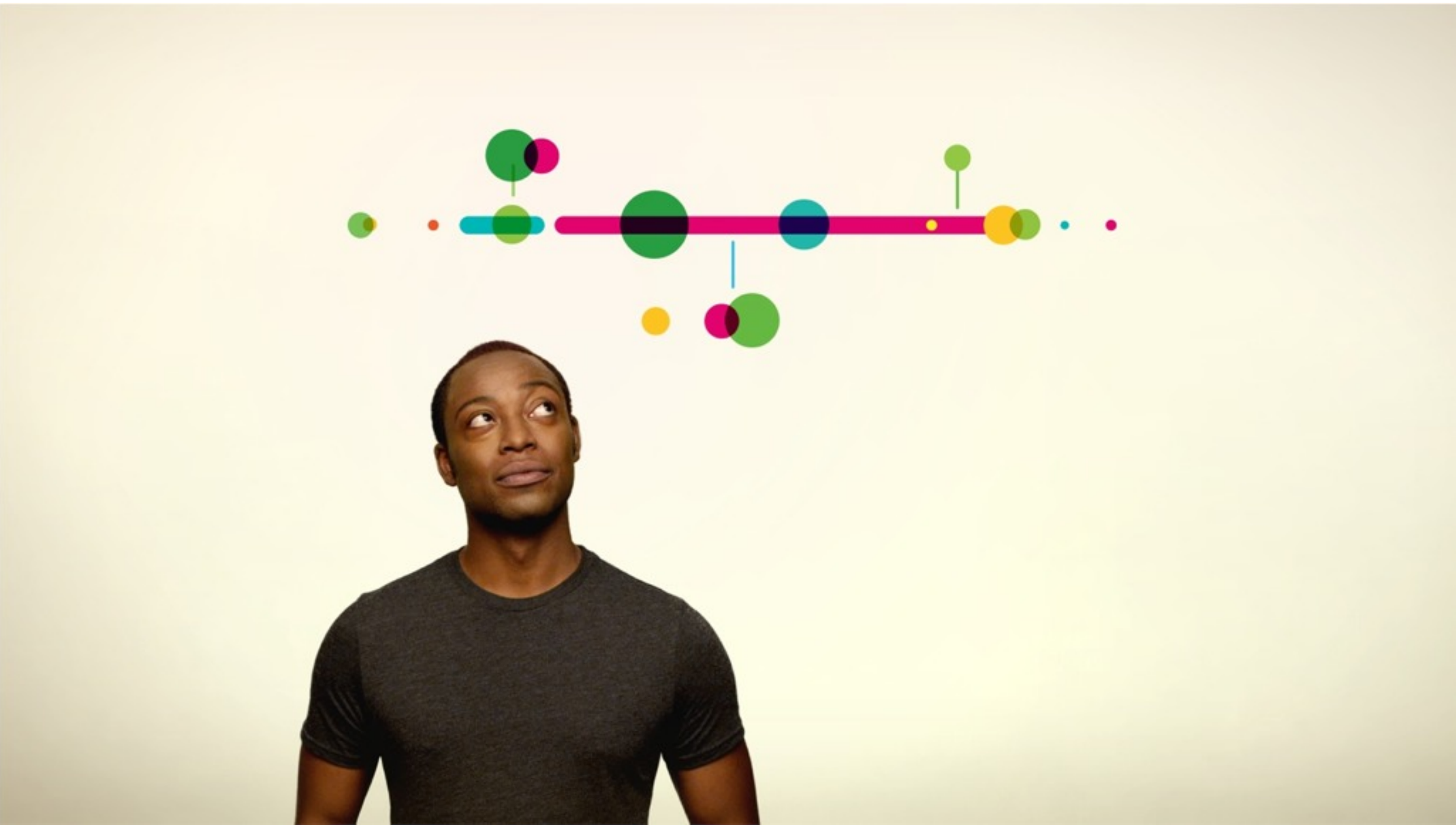
21 Drug Response

49 Carrier Status

57 Traits

$99

Abdominal Aortic Aneurysm
Age-related Macular Degeneration *
Alcohol Dependence
Alopecia Areata
Alzheimer's Disease *
Alzheimer's Disease: Preliminary Research
Ankylosing Spondylitis
Asthma
Atopic Dermatitis
Atrial Fibrillation *
Atrial Fibrillation: Preliminary Research
Attention-Deficit Hyperactivity Disorder
Back Pain
Basal Cell Carcinoma
Behçet's Disease
Bipolar Disorder *
Bipolar Disorder: Preliminary Research
Bladder Cancer
Brain Aneurysm
Breast Cancer *
Breast Cancer Risk Modifiers
Celiac Disease *
Celiac Disease: Preliminary Research
Chronic Kidney Disease *
Chronic Lymphocytic Leukemia
Chronic Obstructive Pulmonary Disease (COPD)
Cleft Lip and Cleft Palate
Cluster Headaches
Colorectal Cancer *
Coronary Heart Disease *
Coronary Heart Disease: Preliminary Research
Creutzfeldt-Jakob Disease
Crohn's Disease *
Developmental Dyslexia
Dupuytren's Disease
Endometriosis
Esophageal Cancer: Preliminary Research
Esophageal Squamous Cell Carcinoma (ESCC) *
Essential Tremor
Exfoliation Glaucoma *
Follicular Lymphoma
Gallstones *
Generalized Vitiligo
Gestational Diabetes
Glaucoma: Preliminary Research
Gout
Hashimoto's Thyroiditis
Hay Fever (Allergic Rhinitis)
Heart Rhythm Disorders (Arrhythmias)
High Blood Pressure (Hypertension)
Hodgkin Lymphoma
Hypertriglyceridemia
Hypothyroidism
Intrahepatic Cholestasis of Pregnancy
Keloid
Kidney Cancer
Kidney Disease
Kidney Stones
Larynx Cancer
Lou Gehrig's Disease (ALS)
Lung Cancer *
Lupus (Systemic Lupus Erythematosus) *
Male Breast Cancer
Male Infertility
Melanoma *
Melanoma: Preliminary Research
Meningioma
Migraines
Multiple Sclerosis *
Myeloproliferative Neoplasms
Narcolepsy
Nasopharyngeal Carcinoma
Neural Tube Defects
Neuroblastoma
Nicotine Dependence
Nonalcoholic Fatty Liver Disease
Obesity *
Obesity: Preliminary Research
Obsessive-Compulsive Disorder
Oral and Throat Cancer
Osteoarthritis
Otosclerosis
Ovarian Cancer
Paget's Disease of Bone
Pancreatic cancer
Parkinson's Disease *
Parkinson's Disease: Preliminary Research
Peripheral Arterial Disease
Placental Abruption
Polycystic Ovary Syndrome
Preeclampsia
Primary Biliary Cirrhosis *
Primary Biliary Cirrhosis: Preliminary Research
Progressive Supranuclear Palsy
Prostate Cancer *
Psoriasis *
Restless Legs Syndrome *
Restless Legs Syndrome: Preliminary Research
Rheumatoid Arthritis *
Sarcoidosis
Sarcoma
Schizophrenia
Scleroderma (Limited Cutaneous Type) *
Scoliosis
Selective IgA Deficiency
Sjögren's Syndrome
Squamous Cell Carcinoma
Stomach Cancer (Gastric Cardia Adenocarcinoma)
Stomach Cancer: Preliminary Research
Stroke
Sudden Cardiac Arrest
Tardive Dyskinesia
Testicular Cancer
Thyroid Cancer
Tourette's Syndrome
Type 1 Diabetes *
Type 2 Diabetes *
Ulcerative Colitis *
Uterine Fibroids
Venous Thromboembolism *



‘The more you know about your DNA, the more you know about yourself’

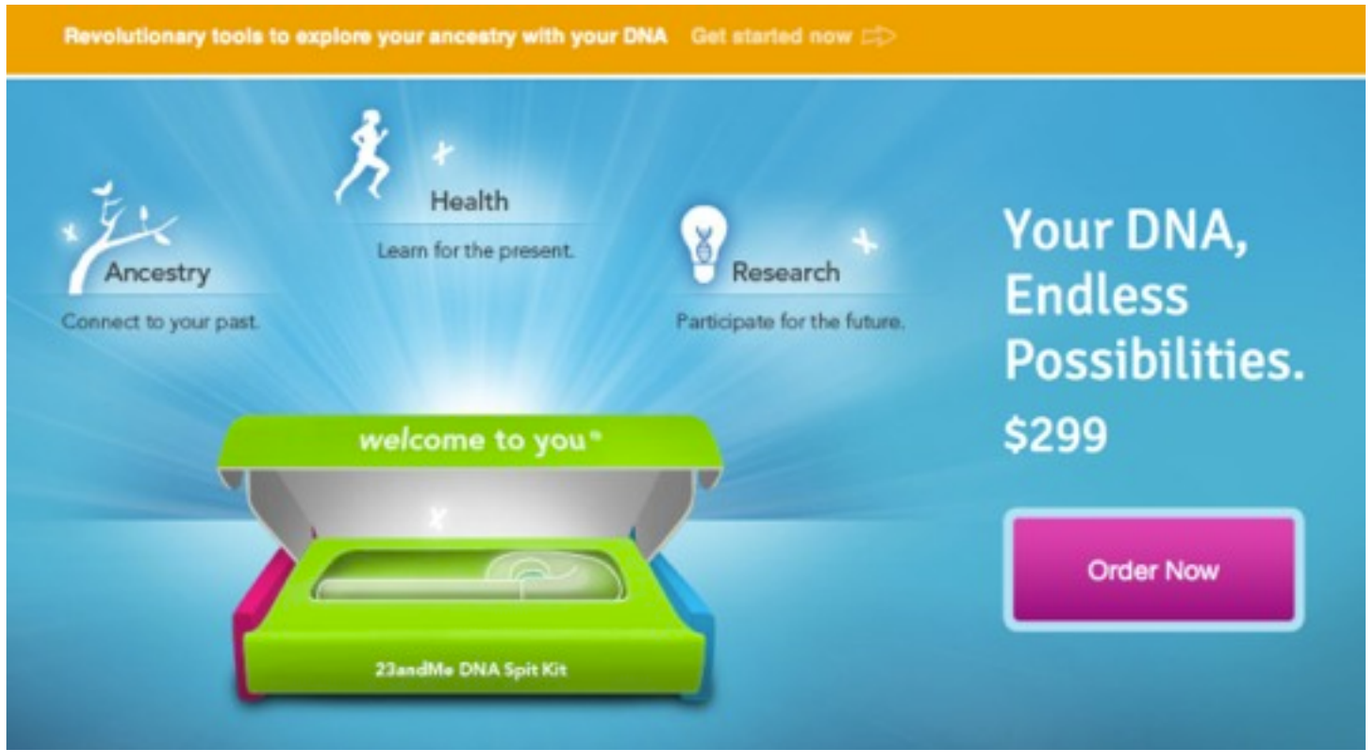
‘The more you know about your DNA, the more you know about yourself’

2006

$999 2008.9→ $399 2012.12→ $99

BIG BROTHER IS
WATCHING YOU

23andMe raised $50 million dollars last year to drop the price of the kits from $999 to $99 and dramatically grow its database.



"This change is not just about a new price point for personal genetic testing. It is about an ambitious plan that could transform medicine for generations to come."

"One million customers can be the tipping point that moves medicine into the molecular era. … A genetic data resource of this magnitude has enormous potential to address unanswered questions related to the contributions of genes, the environment and your health."

- Co-founder&CEO, Anne Wojcicki

SPECIAL SECTION FALL 2013 | NOVEMBER 11, 2013, 1:25 PM | 29 Comments

For $99, Eliminating the Mystery of Pandora's Genetic Box

BY CLAIRE CAIN MILLER

Peter DaSilva for The New York Times

MAPPING GENES Anne Wojcicki, co-founder of 23andMe, a DNA testing company, says genetic science will change health care.

IF DNA is destiny, then Anne Wojcicki is in the right business.

She is the co-founder and chief executive of 23andMe, a Silicon Valley start-up that offers a $99 DNA test, as easy as spitting into a tube, that provides detailed genetic information from disease risk to family lineage.

PREVIOUS ARTICLE
Stepping Up With a Plan to Save American Cities

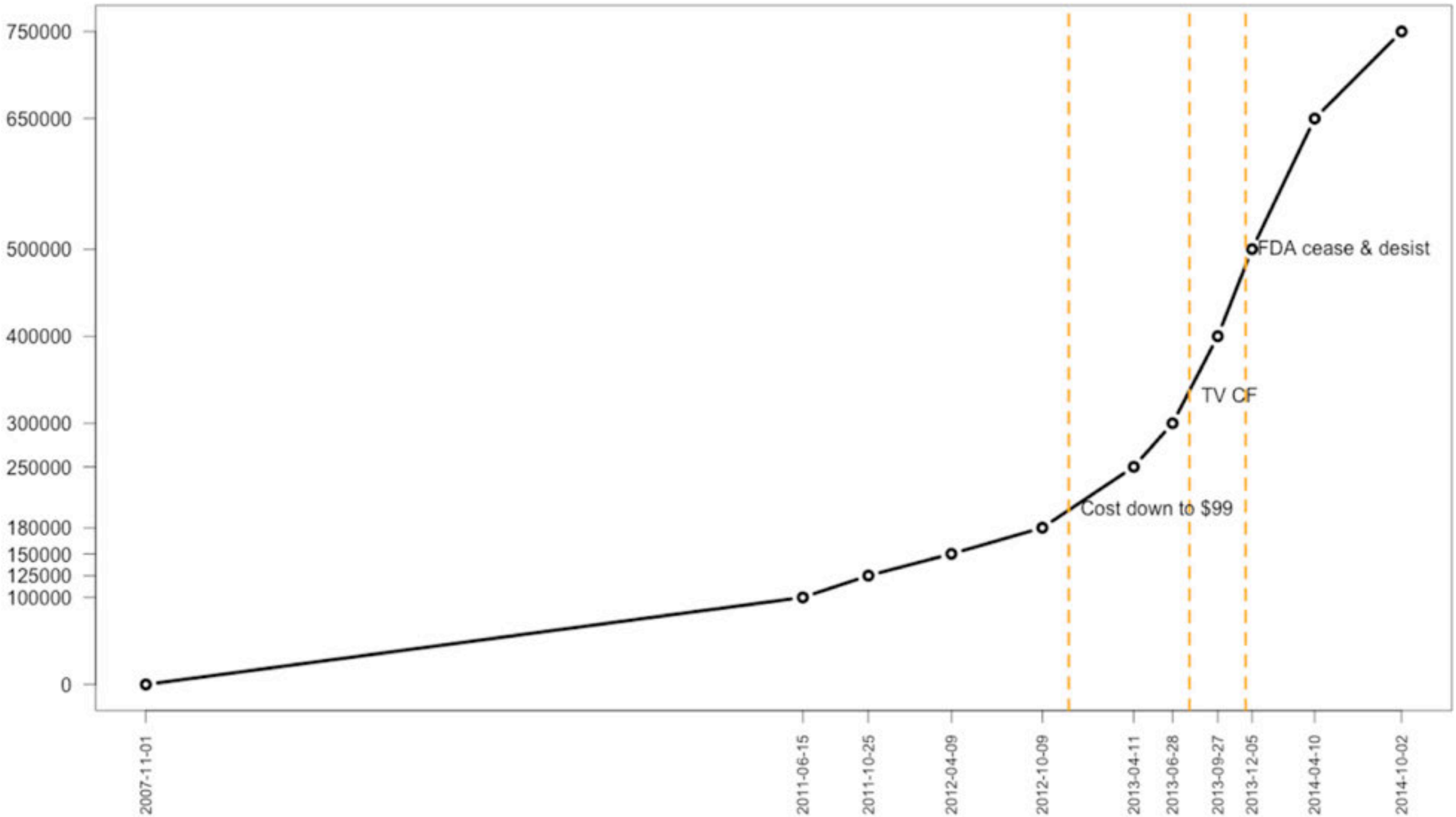
NEXT ARTICLE
Slowing the Revolving Door Between Public and Private Jobs

- In the last fiver years, 23andMe has mapped the genotype of 475,000 people.
- We'll hit a million sometime in the first quarter of next year.

July 29, 2014

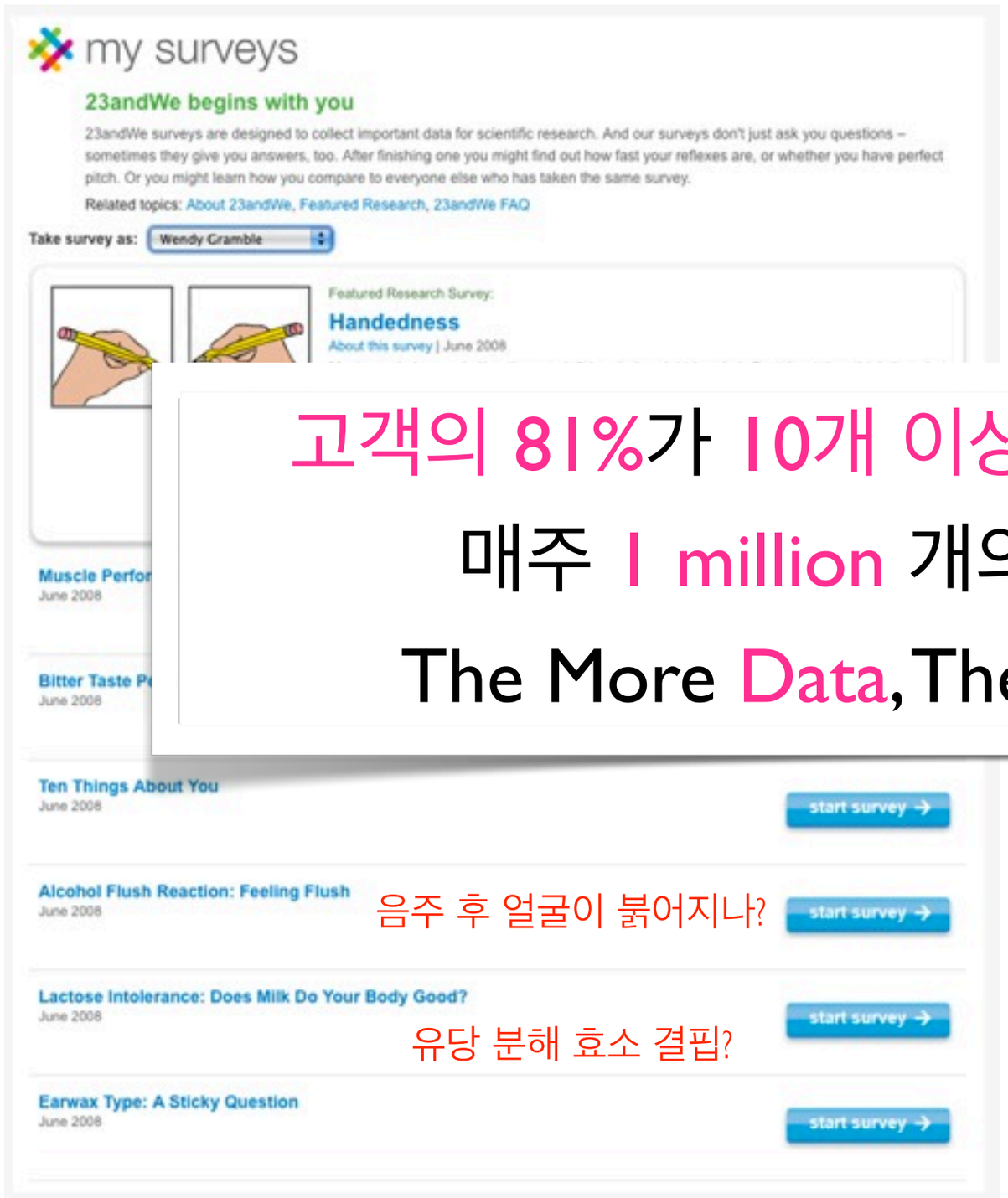
23andMe now has more than 700,000 genotyped customers

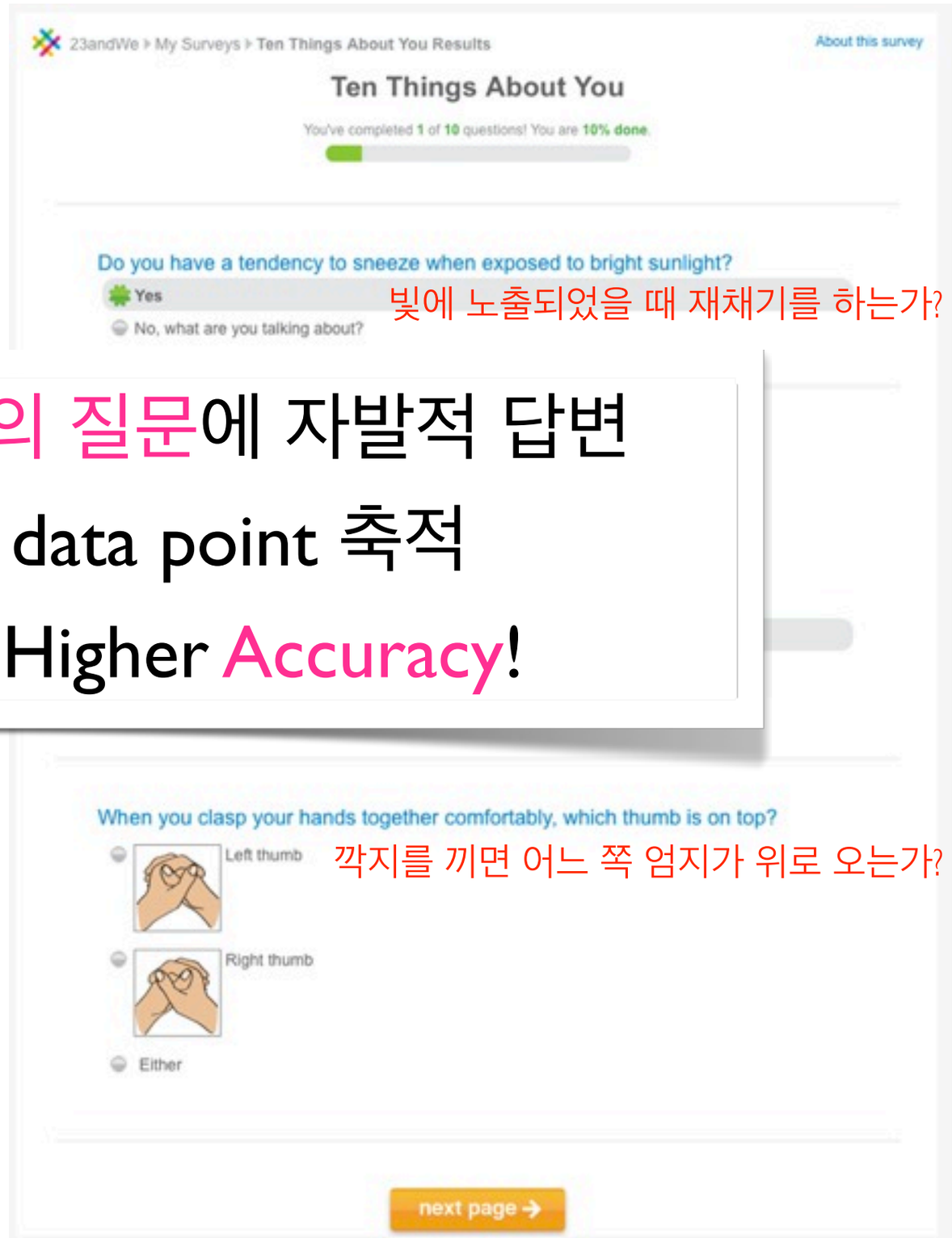
23andMe Customer Growth



http://goldbio.blogspot.kr/2014/12/pg-100.html

고객의 자발적인 참여에 의한 유전학 연구





고객의 81%가 10개 이상의 질문에 자발적 답변

매주 1 million 개의 data point 축적

The More Data, The Higher Accuracy!

https://www.23andme.com/slideshow/research/

Data Business

REUTERS EDITION: U.S. SIGN

HOME BUSINESS MARKETS WORLD POLITICS TECH OPINION BREAKINGVIEWS

23andMe, Genentech to analyze 3,000 Parkinson's genomes

Tue Jan 6, 2015 12:00pm EST

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(Reuters) - Privately held 23andMe Inc and Genentech said on Tuesday they will work together to generate whole genome sequencing data for about 3,000 people with Parkinson's disease, in order to identify new therapeutic targets for treating the degenerative neurological condition.

23andMe, co-founded by Anne Wojcicki, the wife of Google co-founder Sergey Brin, will contribute the genome sequencing and data from its Parkinson's disease community. Genentech, a unit of Roche Holding AG, will work to identify potential therapeutics based on that information.

There is no cure for Parkinson's, which affects about 1 million people in the United States, but some medications can improve symptoms.

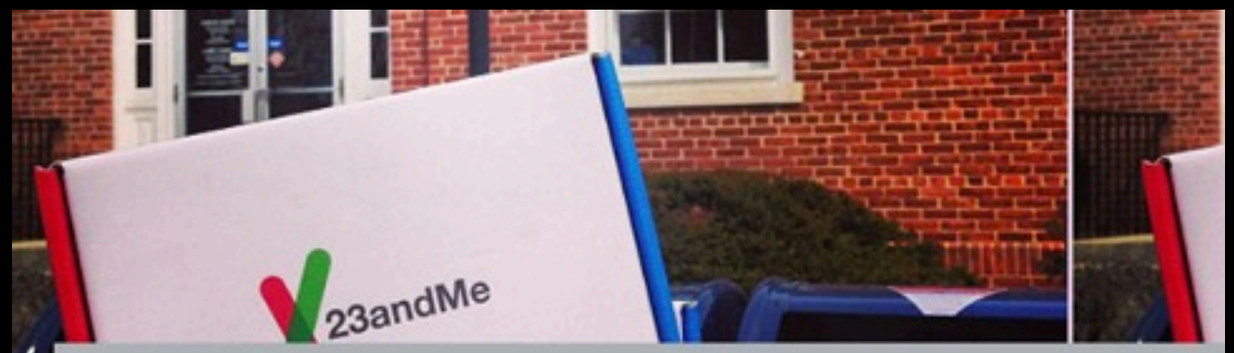
Under the agreement between the two companies, after the multi-year deal ends, 23andMe can conduct additional research on the data and make it available to other Parkinson's researchers. The data will be de-identified and contributed only by individuals who provide explicit permission to 23andMe, the company said.

(Reporting by Caroline Humer; Editing by Leslie Adler)

FILED UNDER: SCIENCE HEALTH

Recommend 83 people recommend this. Be the first of your friends.

January 6, 2015



FAST FEED 147 SHARES

23ANDME GIVES PFIZER ACCESS TO ITS GENOME DATABASE

THE PARTNERSHIP SOUNDS LIKE A WIN-WIN—SO LONG AS 23ANDME'S CLIENT DATA STAYS ANONYMOUS.

BY DAVID LUMB

23andMe, the Mountain View, California-based company that offers a $99 consumer DNA kit, announced an agreement with Pfizer, one of the world's largest pharmaceutical companies and producer of drugs like Lipitor, Zoloft, and Viagra. As part of the deal, Pfizer will get access to 23andMe's database of genetic information gathered through its DNA kits. 23andMe has genotyped more than 800,000 people, 80% of whom have consented to allow their genetic information to be used for research.

23andMe is prohibited by the Food and Drug Administration from offering genetic analysis to consumers, though it can still provide ancestry and raw genetic information for $99. While those consumer fees have supported 23andMe in its early stages, selling access to its ever-expanding genome dataset has been a growth goal for some time.

READ OUR COVER STORY

Inside 23andMe's $99 DNA Revolution

"The long game here is not to make money selling kits, although the kits are essential

January 13, 2015

23andMe has signed 12 other genetic data partnerships beyond Pfizer and Genentech

Above: 23andMe co-founder and CEO Anne Wojcicki
Image Credit: 23andMe

January 14, 2015 7:00 PM
Mark Sullivan

176 99 52 110 429

The consumer genomics company 23andMe announced a couple of major partnerships during the past couple of weeks — one with Genentech last week, and another with drug giant Pfizer this week.

But, as we learned from CEO Anne Wojcicki here at the J.P. Morgan Health care Conference in San Francisco, 23andMe has more genetic data partnerships than just these two — 12 more to be exact.

Wojcicki said her company has actually signed a total of 14 partnerships with private companies and universities.

… If the other 12 deals are anything like the ones with Genentech and Pfizer, they could be very beneficial to 23andMe's financial outlook, and its ability to continue building its database of whole-genome sequencing data.

January 14, 2015

23andMe

your results are ready

We've completed the analysis of your DNA and are ready to load your Health and Ancestry data into your account. We understand that not everyone who purchases the 23andMe service is interested in seeing their health-related data. As such you have the option of not loading your health data in your account. If you prefer to not see health data simply uncheck the box below.

☑ **Please load my (Yoon Sup Choi's) health data.**

Please note that we show this option to everyone and it's not indicative of any of your results.

CONTINUE

Health Risks

Elevated Risk

NAME	CONFIDENCE	YOUR RISK	AVG. RISK	COMPARED TO AVERAGE
Atrial Fibrillation	★★★★	46.9%	27.2%	1.73x
Type 2 Diabetes	★★★★	36.5%	27.8%	1.31x
Type 1 Diabetes	★★★★	4.4%	1.0%	4.30x
Parkinson's Disease	★★★★	1.8%	1.2%	1.43x
Esophageal Squamous Cell Carcinoma (ESCC)	★★★★	0.43%	0.36%	1.21x
Stomach Cancer (Gastric Cardia Adenocarcinoma)	★★★★	0.28%	0.23%	1.22x
Primary Biliary Cirrhosis	★★★★	0.10%	0.08%	1.25x
Male Breast Cancer ♂	★★★			
Stroke	★★★			
Kidney Stones	★★★			
Alopecia Areata	★★★			
Brain Aneurysm	★★★			
Keloid	★★★			
Atrial Fibrillation: Preliminary Research	★★★			
Esophageal Cancer: Preliminary Research	★★★			
Progressive Supranuclear Palsy	★★★			
Primary Biliary Cirrhosis: Preliminary Research	★★★			
Male Infertility ♂	★★★			
Nasopharyngeal Carcinoma	★★★			
Sarcoidosis	★★★			
Hay Fever (Allergic Rhinitis)	★★★			
Behçet's Disease	★★★			
Kidney Cancer	★★★			
Myeloproliferative Neoplasms	★★			

Health Risks

Decreased Risk

NAME	CONFIDENCE	YOUR RISK	AVG. RISK	COMPARED TO AVERAGE
Psoriasis	★★★★	5.0%	11.4%	0.44x
Age-related Macular Degeneration	★★★★	3.1%	6.5%	0.48x
Alzheimer's Disease	★★★★	2.4%	4.0%	0.61x
Restless Legs Syndrome	★★★★	1.5%	2.0%	0.74x
Ulcerative Colitis	★★★★	0.53%	0.77%	0.70x
Melanoma	★★★★	0.25%	2.86%	0.09x
Multiple Sclerosis	★★★★	0.24%	0.34%	0.69x
Exfoliation Glaucoma	★★★★	0.16%	0.75%	0.22x
Celiac Disease	★★★★	0.05%	0.12%	0.44x
Basal Cell Carcinoma	★★★			
Squamous Cell Carcinoma	★★★			
Bipolar Disorder: Preliminary Research	★★★			
Thyroid Cancer	★★★			
Paget's Disease of Bone	★★★			
Pancreatic cancer	★★★			
Hodgkin Lymphoma	★★★			
Schizophrenia	★★★			
Selective IgA Deficiency	★★★			
Melanoma: Preliminary Research	★★★			
Lou Gehrig's Disease (ALS)	★★★			
Follicular Lymphoma	★★★			
Chronic Lymphocytic Leukemia	★★★			
Obesity: Preliminary Research	★★★			
Sarcoma	★★★			
Otosclerosis	★★★			

Health Risks

Typical Risk

NAME	CONFIDENCE	YOUR RISK	AVG. RISK	COMPARED TO AVERAGE
Obesity	★★★★	54.2%	63.9%	0.85x
Coronary Heart Disease	★★★★	52.6%	46.8%	1.12x
Gout	★★★★	24.3%	22.8%	1.07x
Venous Thromboembolism	★★★★	12.8%	12.3%	1.04x
Prostate Cancer ♂	★★★★	11.0%	11.2%	0.98x
Lung Cancer	★★★★	6.9%	8.5%	0.82x
Gallstones	★★★★	6.2%	7.0%	0.88x
Colorectal Cancer	★★★★	5.4%	4.9%	1.11x
Chronic Kidney Disease	★★★★	3.6%	3.4%	1.04x
Rheumatoid Arthritis	★★★★	0.78%	0.90%	0.87x
Crohn's Disease	★★★★	0.52%	0.53%	0.98x
Bipolar Disorder	★★★★	0.10%	0.10%	0.94x
Scleroderma (Limited Cutaneous Type)	★★★★	0.05%	0.07%	0.80x
Breast Cancer ♀	★★★★	0.00%	0.00%	1.00x
Lupus (Systemic Lupus Erythematosus) ♀	★★★★	0.00%	0.00%	1.00x
Bladder Cancer	★★★			
Pulmonary Fibrosis update	★★★			
Coronary Heart Disease: Preliminary Research	★★★			
High Blood Pressure (Hypertension)	★★★			
Migraines	★★★			
Testicular Cancer ♂	★★★			
Chronic Obstructive Pulmonary Disease (COPD)	★★★			
Generalized Vitiligo	★★★			
Dupuytren's Disease	★★★			

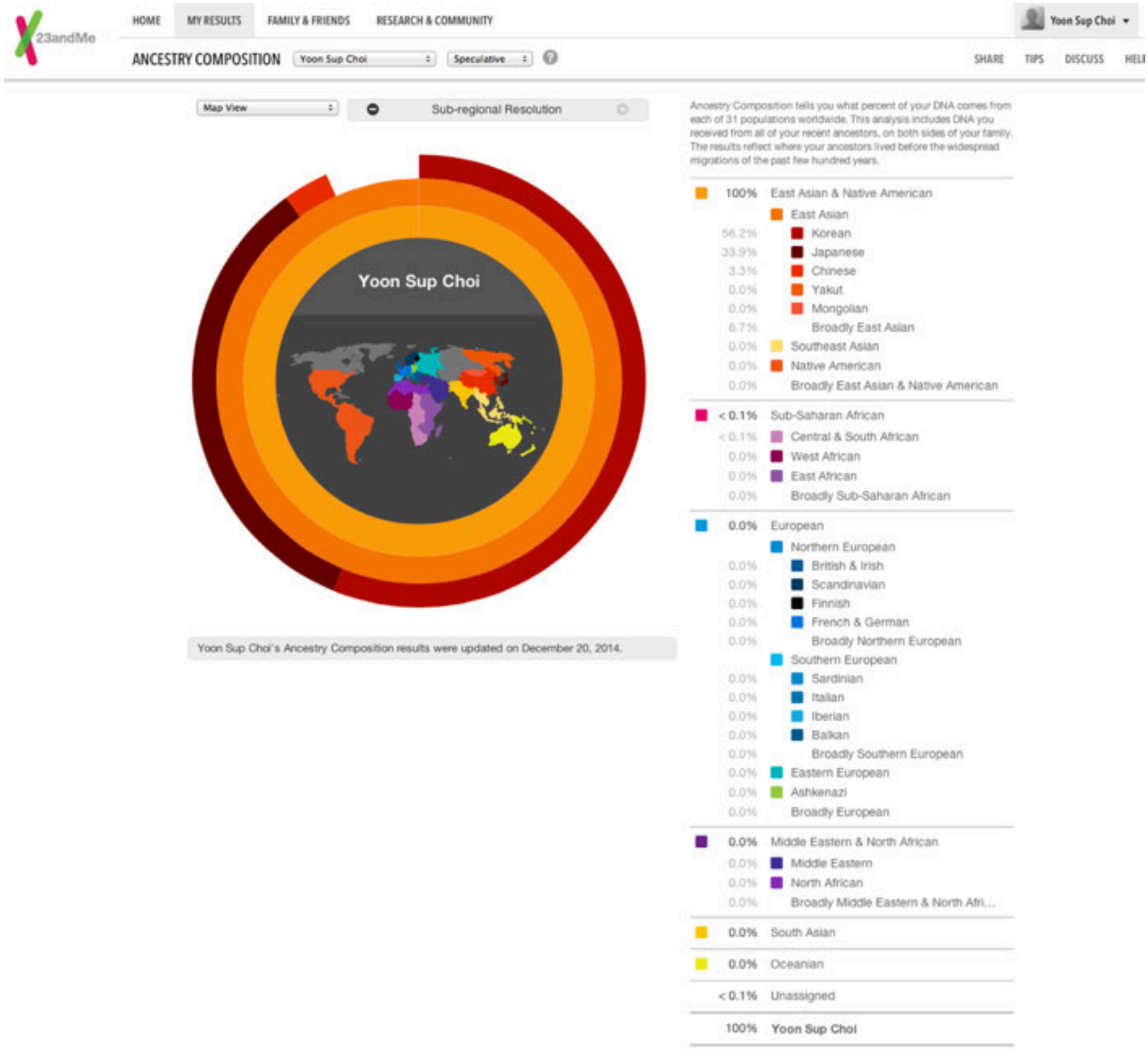
Drug Response

NAME	CONFIDENCE ▾	STATUS
Warfarin (Coumadin®) Sensitivity	★★★★	Increased
Proton Pump Inhibitor (PPI) Metabolism new	★★★★	Intermediate
Alcohol Consumption, Smoking and Risk of Esophageal Cancer	★★★★	Increased
Clopidogrel (Plavix®) Efficacy	★★★★	Reduced
Fluorouracil Toxicity	★★★★	Typical
Sulfonylurea Drug Clearance (Type 2 Diabetes Treatment)	★★★★	Typical
Abacavir Hypersensitivity	★★★★	Typical
Response to Hepatitis C Treatment	★★★★	Typical
Pseudocholinesterase Deficiency	★★★★	Typical
Phenytoin (Dilantin®) Sensitivity (Epilepsy Drug)	★★★★	Typical
Thiopurine Methyltransferase Deficiency	★★★★	Typical
Oral Contraceptives, Hormone Replacement Therapy and Risk of Venous Thromboembolism	★★★★	Not Applicable
Caffeine Metabolism	★★★	Fast Metabolizer
Hepatitis C Treatment Side Effects	★★★	See Report
Metformin Response	★★★	Higher Odds of Positive Response
Warfarin (Coumadin®) Sensitivity: Preliminary Research	★★★	Lower dose, if African-American
Naltrexone Treatment Response	★★	See Report
Response to Interferon Beta Therapy	★★	Increased Odds of Responding
Antidepressant Response	★★	See Report
Statin Response	★★	See Report
Beta-Blocker Response	★★	See Report
Lumiracoxib (Prexige®) Side Effects	★★	Typical Odds
Postoperative Nausea and Vomiting (PONV)	★★	Higher Odds

Traits

NAME	CONFIDENCE ▲	OUTCOME
Alcohol Flush Reaction 음주 후 얼굴이 붉어지는가	★★★★	Flushes
Bitter Taste Perception 쓴 맛을 감지할 수 있나	★★★★	Unlikely to Taste
Earwax Type 귀지 유형	★★★★	Dry
Eye Color 눈 색깔	★★★★	Likely Brown
Hair Curl 곱슬머리 여부	★★★★	Slightly Curlier Hair on Average
Lactose Intolerance 유당 분해 능력	★★★★	Likely Intolerant
Malaria Resistance (Duffy Antigen) 말라리아 저항성	★★★★	Not Resistant
Male Pattern Baldness ♂ 대머리가 될 가능성	★★★★	Decreased Odds
Muscle Performance 근육 퍼포먼스	★★★★	Unlikely Sprinter
Non-ABO Blood Groups 혈액형	★★★★	See Report
Norovirus Resistance 노로바이러스 저항성	★★★★	Not Resistant
Resistance to HIV/AIDS HIV 저항성	★★★★	Not Resistant
Smoking Behavior 흡연 중독 가능성	★★★★	If a Smoker, Likely to Smoke More
Adiponectin Levels	★★★	See Report
Asparagus Metabolite Detection	★★★	Higher Odds of Detecting
Biological Aging	★★★	See Report
Birth Weight	★★★	See Report
Blood Glucose	★★★	5.18 mmol/L on Average
Breastfeeding and IQ	★★★	See Report
C-reactive Protein Level	★★★	See Report
Caffeine Consumption	★★★	See Report
Childhood and Adolescent Growth	★★★	See Report
Chronic Hepatitis B	★★★	See Report
Eye Color: Preliminary Research	★★★	See Report

Ancestry Composition

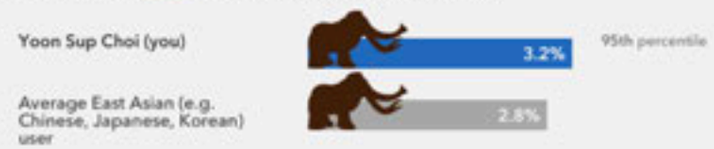


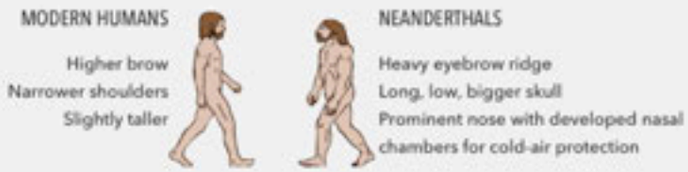
Neanderthal Ancestry

This lab estimates your genome-wide percentage of Neanderthal ancestry

Got Neanderthal DNA?

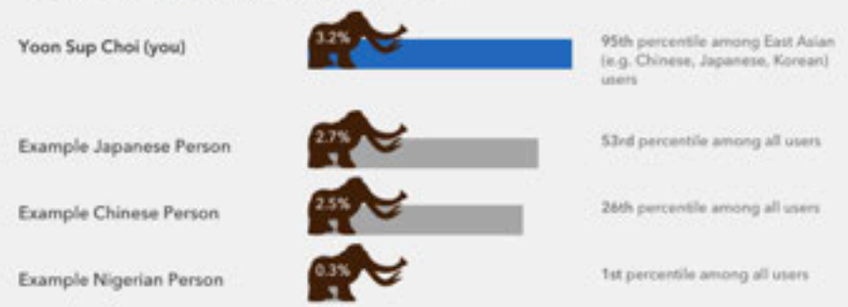
An estimated 3.2% of your DNA is from Neanderthals.





Friends & Family

You are ranked 1st among your friends. Invite more friends



Genetic Evidence for Neanderthals

From bones like these three (Vi33.16, Vi33.25, Vi33.26) found in the Vindija cave in Croatia, scientists extracted Neanderthal DNA. Using these samples they painstakingly assembled the Neanderthal genome sequence.

More about Neanderthals

Neanderthals were a group of humans who lived in Europe and Western Asia. They are the closest evolutionary relatives of modern humans, but they went extinct about 30,000 years ago. The first Neanderthals arrived in Europe as early as 600,000 to 350,000 years ago. Neanderthals – Homo neanderthalensis – and modern humans – Homo sapiens – lived along side each other for thousands of years. Genetic evidence suggest that they interbred and although Neanderthals disappeared about 30,000 years ago, traces of their DNA – between 1 percent and 4 percent – are found in all modern humans outside of

So what, I'm a caveman?

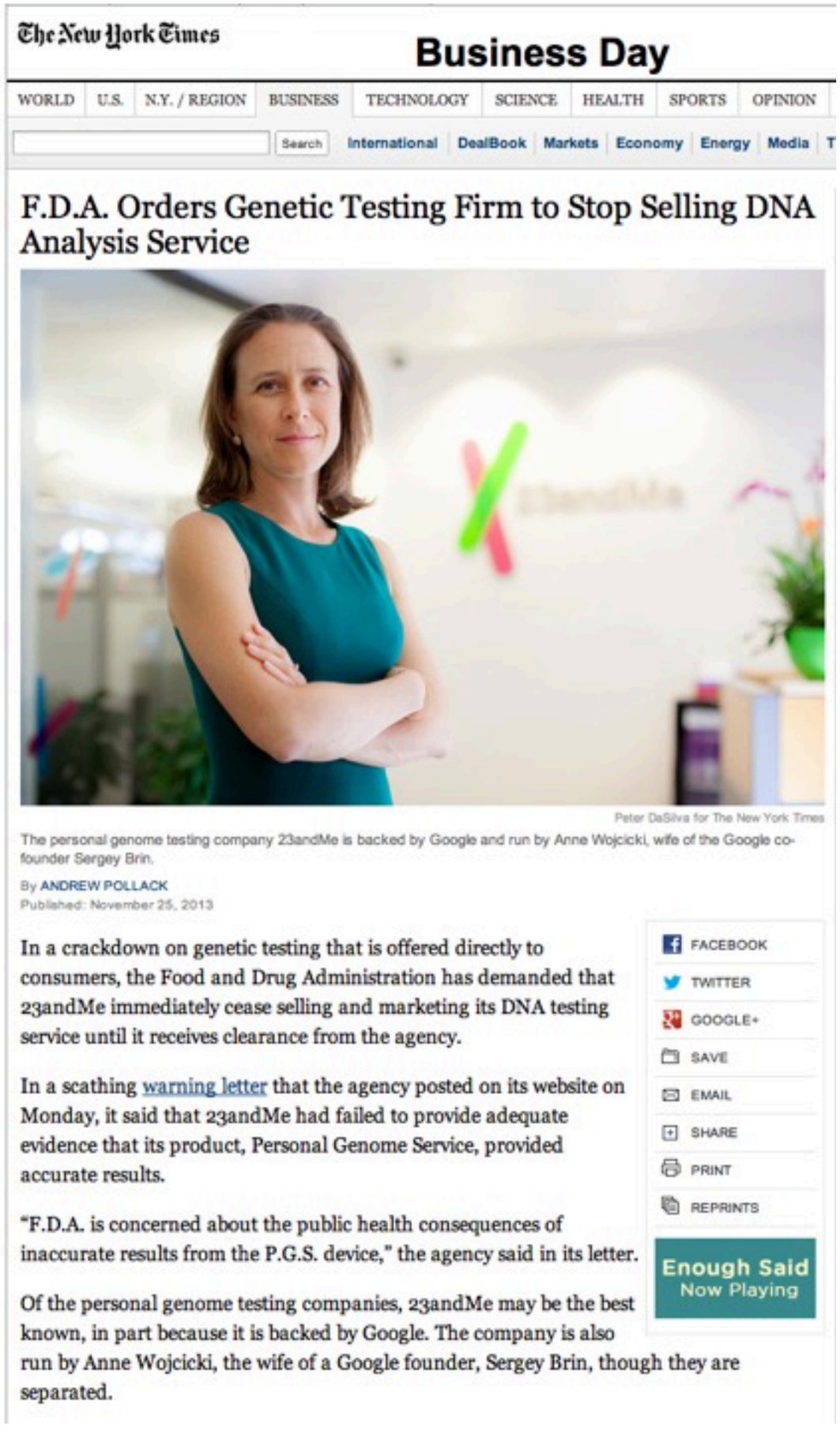
Actually yes, but that has little to do with the percentage of Neanderthal DNA in your genome. Our perception of Neanderthals as big oafs is clouded by our own notion of superiority and pop culture caricatures. How we are different and why modern humans survived and Neanderthals didn't is still mostly a mystery.

Neanderthal and proud?

Whatever your Neanderthal percentage, there's a T-shirt for you and your family. Check it out.

What does this really mean?

There are many intriguing theories about what traits the smidgen of Neanderthal DNA may have imparted on modern humans, but we don't know yet if having a little more than average Neanderthal DNA could explain why someone is extra brawny, short or boorish. Those traits might just be regular human characteristics.



The New York Times

Business Day

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F.D.A. Orders Genetic Testing Firm to Stop Selling DNA Analysis Service

Peter DaSilva for The New York Times

The personal genome testing company 23andMe is backed by Google and run by Anne Wojcicki, wife of the Google co-founder Sergey Brin.

By ANDREW POLLACK
Published: November 25, 2013

In a crackdown on genetic testing that is offered directly to consumers, the Food and Drug Administration has demanded that 23andMe immediately cease selling and marketing its DNA testing service until it receives clearance from the agency.

In a scathing warning letter that the agency posted on its website on Monday, it said that 23andMe had failed to provide adequate evidence that its product, Personal Genome Service, provided accurate results.

"F.D.A. is concerned about the public health consequences of inaccurate results from the P.G.S. device," the agency said in its letter.

Of the personal genome testing companies, 23andMe may be the best known, in part because it is backed by Google. The company is also run by Anne Wojcicki, the wife of a Google founder, Sergey Brin, though they are separated.

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- 분석 결과의 정확성에 대한 FDA의 검증 필요
- Analytic & clinical validation data 제출 지연
- 외부적 이슈들

HEALTHWARE

245 SHARES

23ANDME EXPANDS INTO CANADA

THE GENETICS TESTING SERVICE HEADS NORTH.

BY CHRIS GAYOMALI

While the Food and Drug Administration slowly mulls the legality of the low-cost genetics tests offered by 23andMe, the Mountain View-based startup is taking its services to a place where the FDA's jurisdiction doesn't apply. On Wednesday, the company announced that it was expanding into Canada, allowing anyone who wants it to send in small saliva samples to receive comprehensive DNA reports interpreting both their family ancestry and—unlike Americans—their genetic health risks.

In an announcement, 23andMe said Canadians will be privy to "108 health-related reports," including "genetic risk factors for various health conditions, drug response, trait reports, and inherited conditions." Some 20,000 Canadians have already taken advantage of its services, which cost $199.

MORE

- **Inside 23andMe Founder Anne Wojcicki's $99 DNA Revolution**
- **FDA to 23andMe Founder Anne Wojcicki: Stop Marketing $99 DNA Test Or Face Penalties**
- **Why 23andMe Terrifies Health Insurance Companies**

23andMe, which was founded by biologist Anne Wojcicki in 2006 (you can read our cover story about the company here), recently made inroads with American regulators. In June, the FDA accepted a single genetics-related health report, which will help establish legal parameters for forthcoming consumer products. "Once cleared, we expect this submission will provide 23andMe with a foundation to accelerate the process for future submissions," a company representative told *Fast*

October 1, 2014

23andMe expands to the UK despite US restrictions

The same tests that the company isn't allowed to market in the US w sold in the UK

By Elizabeth Lopatto on December 1, 2014 07:00 pm Email @mslopatto

23andMe, the genetics company, is expanding its Personal Genome Service to the UK market. Perhaps wary of the troubles that have plagued the company in the US, 23andMe notes in its UK press release that its services are not diagnostic. That doesn't stop the company from promising to reveal risk factors and genes for sickle cell anemia, cystic fibrosis, Alzheimer's disease, and Parkinson's disease — using the same health reports that

December 1, 2014

23andMe
Health
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FDA Authorizes 23andMe To Market Genetic Testing For Bloom Syndrome

Posted Feb 19, 2015 by Sarah Buhr (@sarahbuhr)

510 SHARES

The U.S. Food and Drug Administration has given 23andMe clearance to begin selling kits for the genetic testing of Bloom Syndrome.

This is a rare recessive gene disorder that is characterized by shorter height and a predisposition to develop cancer. Parents of children with Bloom Syndrome don't exhibit any symptoms of the disorder.

23andMe's direct-to-consumer genetic test allows someone to see if they have a specific gene variant for Bloom Syndrome and helps parents know if they could potentially pass on the gene that would cause their children to have the disorder.

This is a significant ruling from the FDA. 23andMe had been ordered to stop selling the health reports associated with the at-home testing kits after not meeting the necessary FDA approval to do so back in 2013. The kits tested for 254 different kinds of disease markers. The FDA had classified these kits as medical devices for that reason and determined that it required regulatory approval before genetic information regarding health could be given to the public. This is the first time the FDA has approved this sort of test without a doctor's approval.

> *"It gives 23andMe a regulatory framework for future submissions."*
> — Anne Wojcicki

The FDA has classified the Bloom Syndrome carrier screening tests as class II, meaning the kits have special controls in place for direct-to-consumer marketing. The kits are also intended for

CrunchBase

23andMe

FOUNDED 2006

OVERVIEW
A startup co-founded by Linda Avey and Anne Wojcicki, the wife of Google co-founder Sergey Brin, 23andMe has plans to make the human genome searchable. Brin, along with Google, gave 23andMe $3.9 million as part of a series A in May of 2007. The company was named after the number of chromosome pairs in humans. They aim to help people understand what their genes mean by indexing them and highlighting ...

LOCATION
Mountain View, California

CATEGORIES
Search, Biotechnology

WEBSITE
http://23andme.com

Full profile for 23andMe

Anne Wojcicki +

2015.2.19

의의

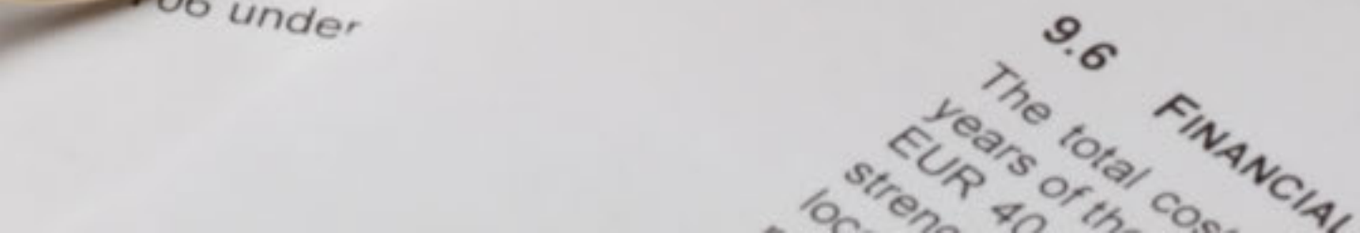
- ‘블룸 증후군’ 이라는 하나의 질병에 대한 유전자 테스트를 FDA 승인
- 최초로 승인 받은 DTC (Direct-to-Consumer) 유전자 테스트
- Class II 로 분류되어, 유사 DTC 테스트도 향후 시장 출시 전 심사 면제

“몇년 전만 하더라도 꿈도 꿀 수 없는 일이다”

전망

- 23andMe 의 다른 유전자 테스트들도 FDA 등록 러쉬 예상
- 개인 유전자 분석 (PGS) 시장의 본격적인 개화
- 한국 식약처 포함, 전세계 규제 기관에도 직간접적 영향 예상

LIFE INSURANCE



Diagnosis by Computers

수퍼 컴퓨터가 환자를 진단한다

Bone Soup Is Back With a Vengeance

TECH ROBOTICS

5 Very Smart People Who Think Artificial Intelligence Could Bring the Apocalypse

Victor Luckerson @VLuck | Dec. 2, 2014

'The end of the human race'

Theoretical physicist Stephen Hawking poses for a picture ahead of a gala screening of the documentary 'Hawking', a film about the scientist's life.
AFP/Getty Images

On the list of doomsday scenarios that could wipe out the human race, super-smart killer robots rate pretty high in the public consciousness. And in scientific circles, a growing number of artificial intelligence experts agree that humans will eventually create an artificial intelligence that can think beyond our own capacities. This moment, called the singularity, could create a utopia in which robots automate common forms of labor and humans relax amid bountiful resources. Or it could lead the artificial intelligence, or AI, to exterminate any creatures it views as competitors for control of the Earth—that would be us. Stephen Hawking has long seen the latter as more likely, and he made his thoughts known again in a recent interview with the BBC. Here are some comments by Hawking and other very smart people who agree that, yes, AI could be the downfall of humanity.

"It would take off on its own and re-design itself at an ever increasing rate. Humans, who are limited by slow biological evolution, couldn't compete, and would be superseded."
- Stephen Hawking, Dec 2014

Elon Musk's secret fear: Artificial Intelligence will turn deadly in 5 years

IMAGE: FLICKR, TED CONFERENCE

BY ADARIO STRANGE

NOV 18, 2014

There's plenty of debate over the singularity — a hypothetical future moment where software becomes self-aware and smart beyond our capacity to understand. Some say it will be a boon for humanity; some foresee an Artificial Intelligence-driven apocalypse.

We already knew that Elon Musk was in the latter camp. Now we know that the SpaceX and Tesla entrepreneur thinks the A.I. doom is approaching faster than anyone suspects — within the next 5-10 years.

SEE ALSO: 10 million UK jobs at risk from computers and robots, study says

It all started last Friday, when noted virtual reality pioneer Jaron Lanier was featured on publisher John Brockman's site, Edge.org, discussing the potential threat of artificial intelligence in a post titled "The Myth of A.I." Following his thoughts are comments from a

"If I had to guess at what our biggest existential threat is, it's probably that.

... With artificial intelligence we are summoning the demon.

... there should be some regulatory oversight, maybe at the national and international level"

- Elon Musk, Nov 2014

The Switch

Bill Gates on dangers of artificial intelligence: ‘I don’t understand why some people are not concerned’

By Peter Holley January 29 Follow @peterlt

Bill Gates joined Reddit for an AMA on Wednesday. (Tobias Schwarz/AFP/Getty Images)

Bill Gates is a passionate technology advocate (big surprise), but his predictions about the future of computing aren't uniformly positive.

During a wide-ranging Reddit "Ask me Anything" session -- one that touched upon everything from his biggest regrets to his favorite spread to lather on bread -- the Microsoft co-founder and billionaire philanthropist outlined a future that is equal parts promising and ominous.

Midway through the discussion on Wednesday, Gates was asked what personal computing will look like in 2045. Gates responded by asserting that the next 30 years will be a time of rapid progress.

"Even in the next 10 problems like vision and speech understanding and

Most Read Business

1 Missouri Republicans are trying to ban food stamp recipients from buying steak and seafood

2 This conservative group is tired of being

""I am in the camp that is concerned about super intelligence... A few decades after that though the intelligence is strong enough to be a concern.

I agree with Elon Musk and some others on this and don't understand why some people are not concerned.""

- Bill Gates, Jan 2015

The Washington Post

Apple co-founder on artificial intelligence: ‘The future is scary and very bad for people’

By Peter Holley March 24 Follow @peterilt

Steve Wozniak speaks at the Worldwebforum in Zurich on March 10. (Steffen Schmidt/European Pressphoto Agency)

The Super Rich Technologists Making Dire Predictions About Artificial Intelligence club gained another fear-mongering member this week: Apple co-founder Steve Wozniak.

In an interview with the Australian Financial Review, Wozniak joined original club members Bill Gates, Stephen Hawking and Elon Musk by making his own casually apocalyptic warning about machines superseding the human race.

"Like people including Stephen Hawking and Elon Musk have predicted, I agree that the future is scary and very bad for people," Wozniak said. "If we build these devices to take care of everything for us, eventually they'll think faster than us and they'll get rid of the slow humans to run companies more efficiently."

Most Read Business

1 Missouri Republicans are trying to ban food stamp recipients from buying steak and seafood

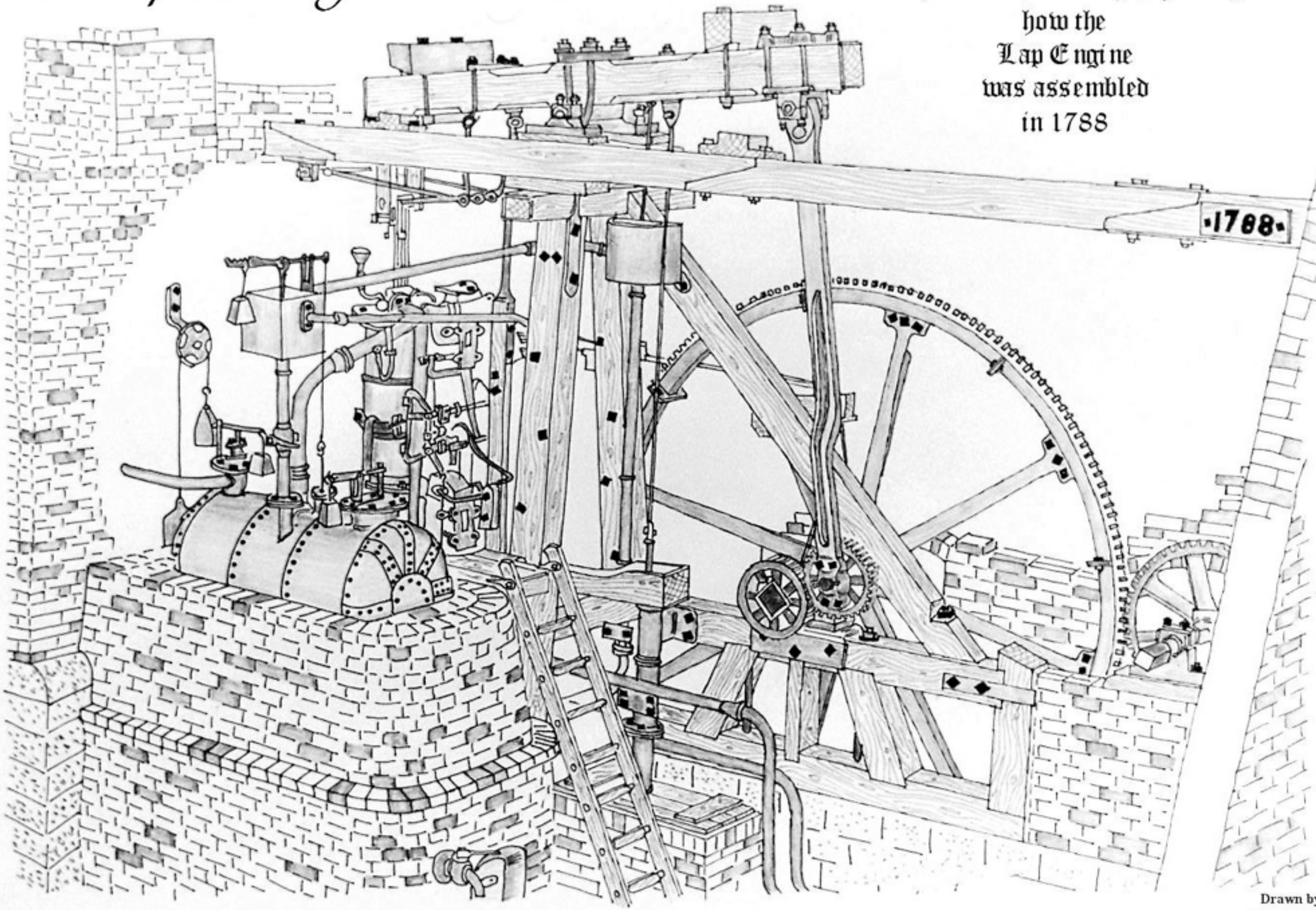
2 This conservative group is tired of being accused of climate denial — and is fighting back

"If we build these devices to take care of everything for us, eventually they'll think faster than us and they'll get rid of the slow humans to run companies more efficiently."

- Steve Wozniak, March 2015

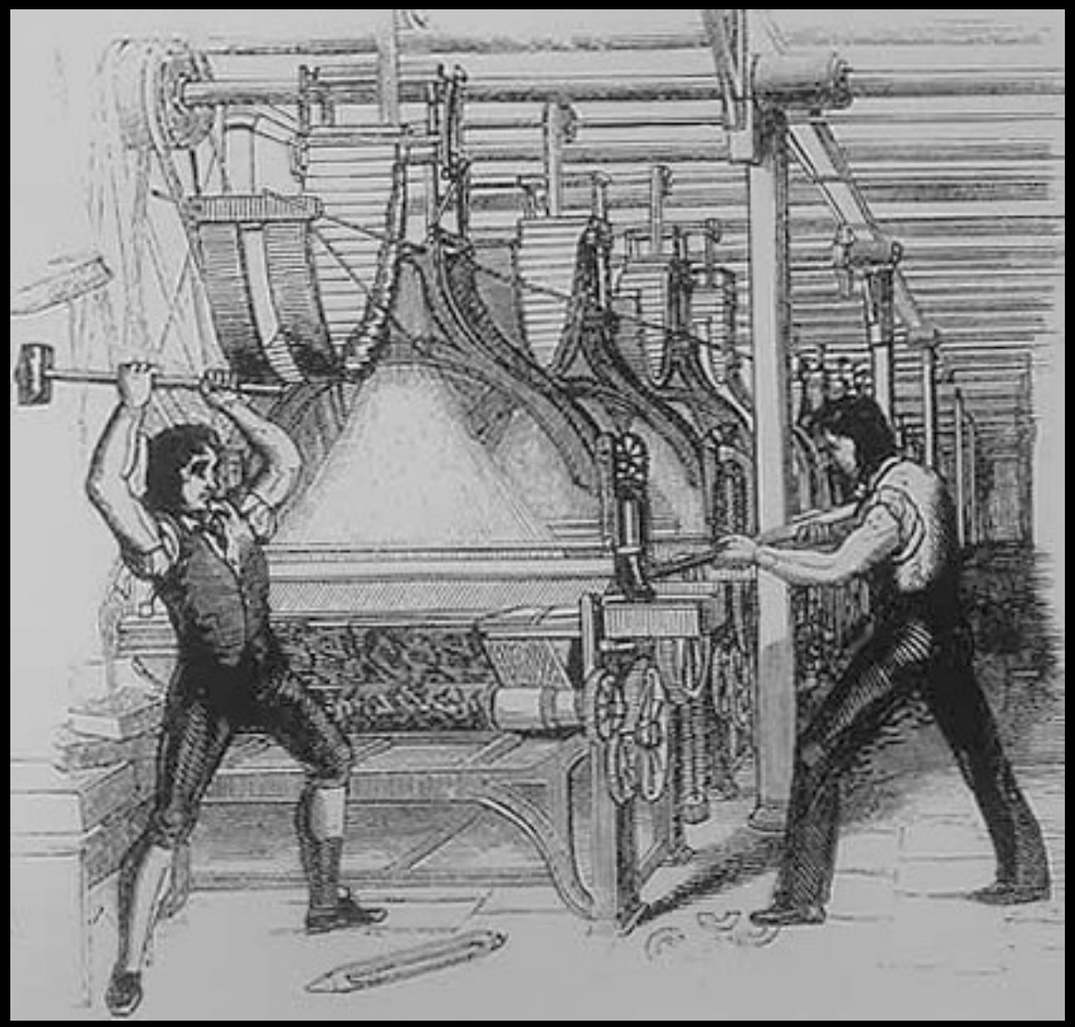
Ten horsepower engine

A Pictorial Drawing Showing
how the
Lap Engine
was assembled
in 1788



Drawn by
David K Hul
March 198

Luddites in the 1810's



CULTURE TECH WEB REPORT

18 COMMENTS

AP's 'robot journalists' are writing their own stories now

By Ross Miller on January 29, 2015 11:55 am Email @ohnorosco

(Typing robot photo by Shutterstock)

Minutes after Apple released its record-breaking quarterly earnings this week, the Associated Press published (by way of *CNBC*, *Yahoo*, and others) "Apple tops Street 1Q forecasts." It's a story without a byline, or rather, without a *human* byline — a financial story written and published by an automated system well-versed in the AP Style Guide. The AP implemented the system six months ago and now publishes 3,000 such stories every quarter — and that number is poised to grow.

Quarterly earnings are a necessity for business reporting — and it can be both monotonous and stressful, demanding a combination of accuracy and speed. That's

- AP 통신: 로봇이 인간 대신 기사를 작성
- 초당 2,000 개의 기사 작성 가능
- 기존에 300개 기업의 실적 → 3,000 개 기업을 커버

Vinod Khosla

Founder, 1st CEO of Sun Microsystems
Partner of KPCB, CEO of Khosla Ventures
Legendary Venture Capitalist in Silicon Valley

OPINION

Do We Need Doctors Or Algorithms?

VINOD KHOSLA

Tuesday, January 10th, 2012

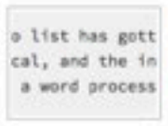
76 Comments

Editor's note: *This is Part II of a guest series written by legendary Silicon Valley investor **Vinod Khosla**, the founder of **Khosla Ventures**. In **Part I**, he laid the groundwork by describing how artificial intelligence is a combination of human and computer capabilities. In Part III, he will talk about how technology will sweep through education.*

I was asked about a year ago at a talk about energy what I was doing about the other large social problems, namely health care and education. Surprised, I flippantly responded that the best solution was to get rid of doctors and teachers and let your computers do the work, 24/7 and with consistent quality.

Later, I got to cogitating about what I had said and why, and how embarrassingly wrong that might be. But the more I think about it the more I feel my gut reaction was probably right. The beginnings of "Doctor Algorithm" or Dr. A for short, most

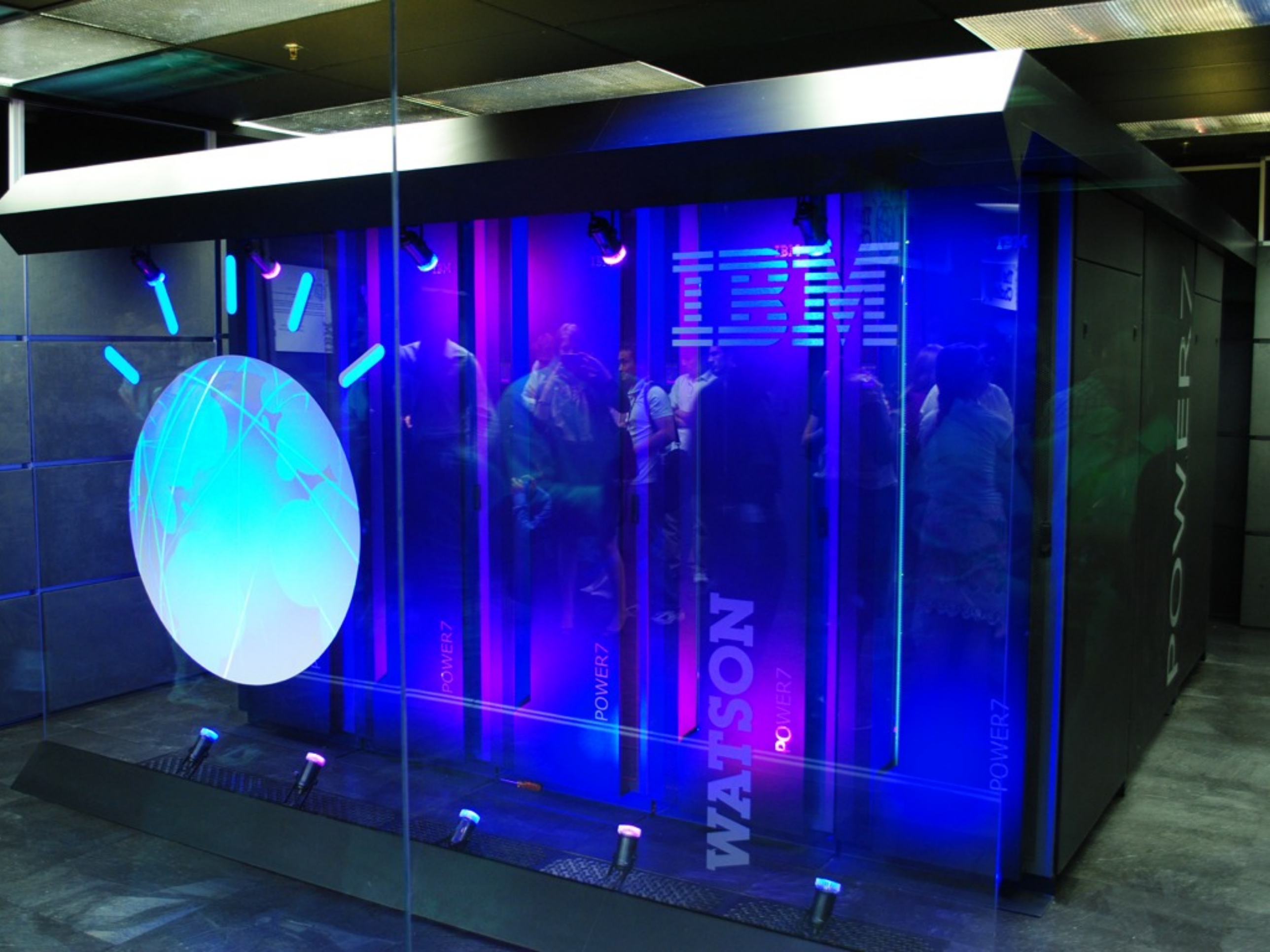
TRENDING STORIES



Draft Is A Word Processor For The Modern Age

Get More Out Of Your Car With Automatic

"Technology will replace 80% of doctors"


IBM
POWER7
WATSON
POWER7
POWER7
POWER7

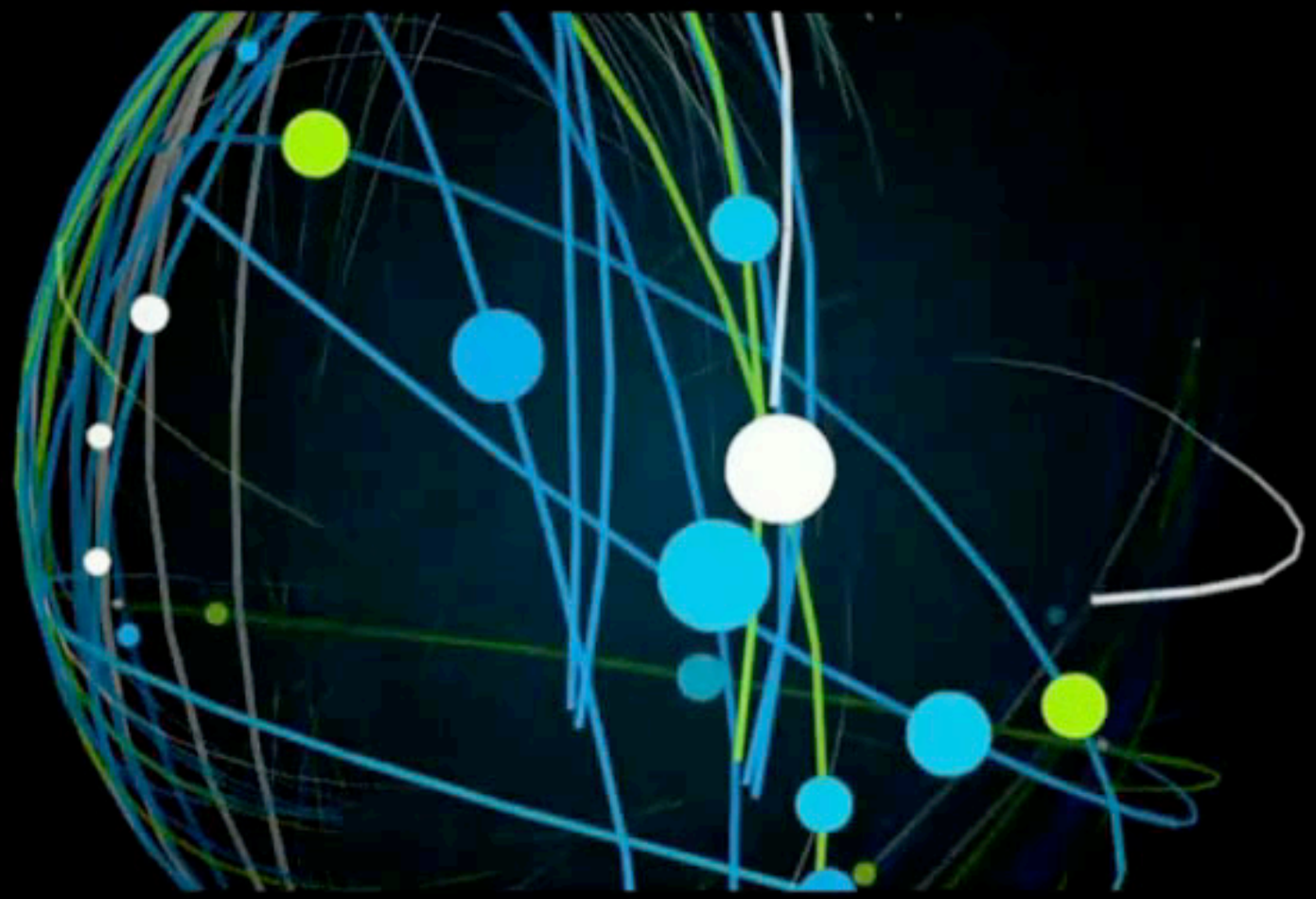
Jeopardy!

2011년 인간 챔피언 두 명 과 퀴즈 대결을 벌여서 압도적인 우승을 차지

“Its largest airport was named for a World War II hero;
its second largest, for a World War II battle"

“What is Chicago”

IBM Watson on Jeopardy!



- 신뢰도에 따라 여러 가지 답을 제공
- 답에 대한 확신을 buzz threshold 로 보여줌

IBM Watson on Jeopardy!

Memorial Sloan Kettering Cancer Center

- 세계에서 가장 오래되고, 가장 큰 사립 암 병원
- Watson은 2012년 3월부터 '레지던트' 생활
- 폐암을 시작으로, 유방암/전립선암으로 확대 계획
- 의사와 유사한 '트레이닝' 과정을 수천 시간 거침

IBM Watson on Medicine

Watson learned...

600,000 pieces of medical evidence

2 million pages of text from 42 medical journals and clinical trials

69 guidelines, 61,540 clinical trials

+

1,500 lung cancer cases

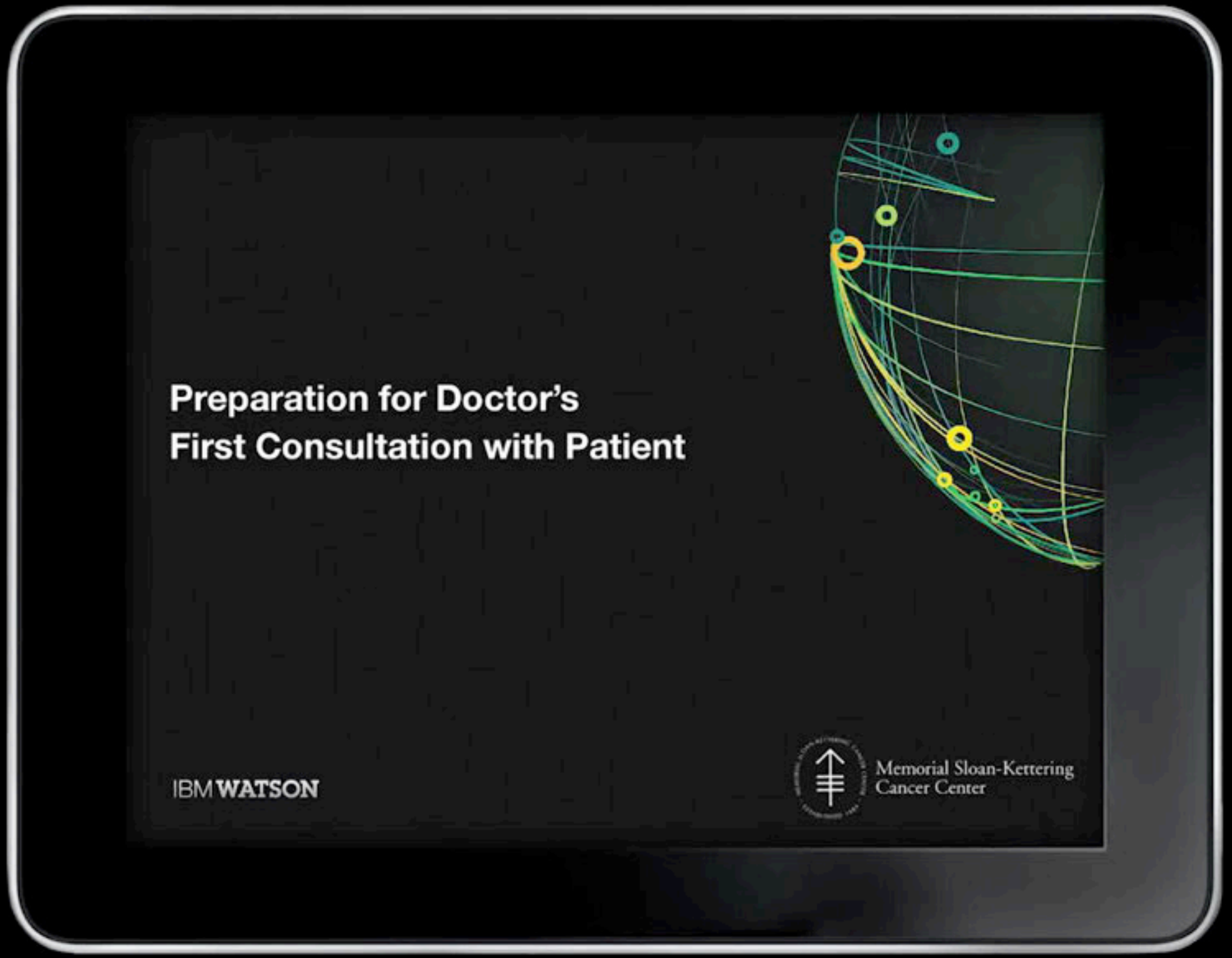
physician notes, lab results and clinical research

+

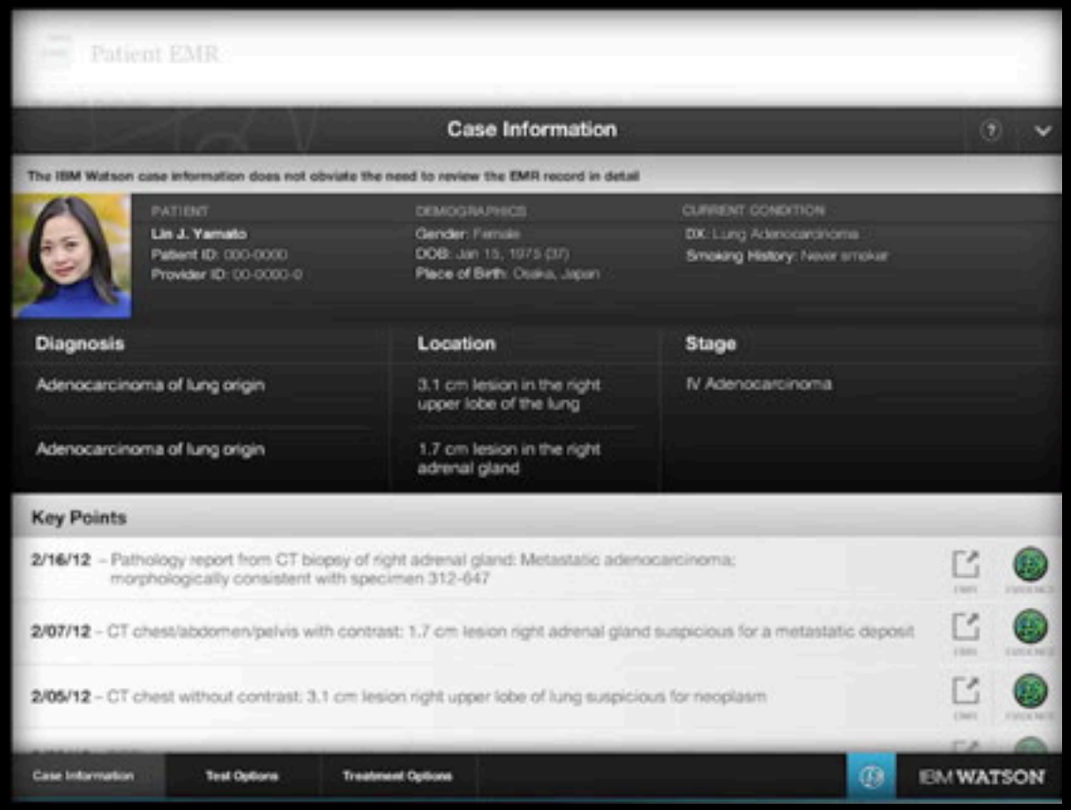
14,700 hours of hands-on training

어떻게 사용되나?

- Interactive Care Insights for Oncology
  - 환자를 치료하기 위해 가능한 치료법들을 의사에게 추천
  - 방대한 의학/임상 데이터, 환자 진단 정보 등을 고려하여 다수의 적절한 치료법 제안
- Interactive Care Guide & Interactive Care Reviewer
  - 의료보험사의 입장에서, 의사가 제안한 치료법에 의료보험 급여를 지급할 것인지 판단
  - 의사가 제시하는 치료법과 Watson이 제시하는 치료법을 비교
  - 거대 민간 보험사 WellPoint 에서 사용 중

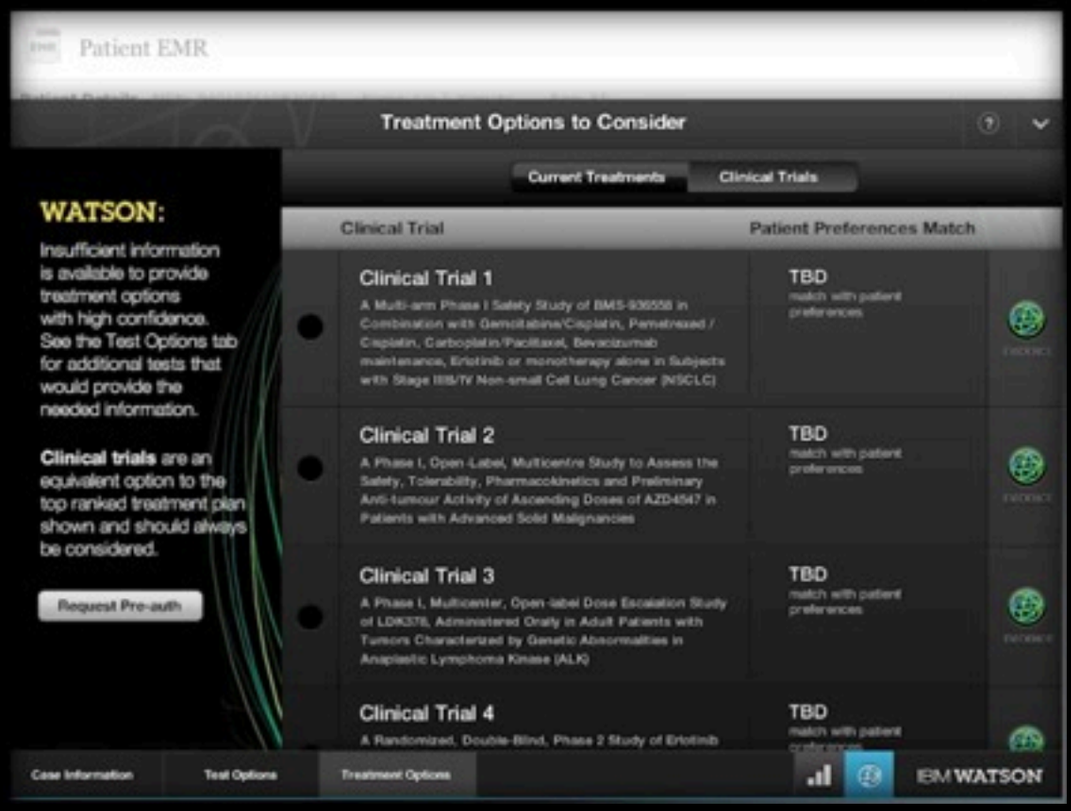


- 의사는 진료 전에 (환자의 데이터를 일일이 찾지 않고) Watson으로 치료/검사 옵션을 살펴봄
- 환자의 EMR(전자 의료 기록)에 Watson 기능이 통합되어 있음
- 환자에게 어떤 검사를 해야 하는지 (reference와 함께) 제시하여 줌
- 검사 결과를 반영, '치료 옵션(treatment options)'을 신뢰도 및 근거와 함께 제시하여 줌

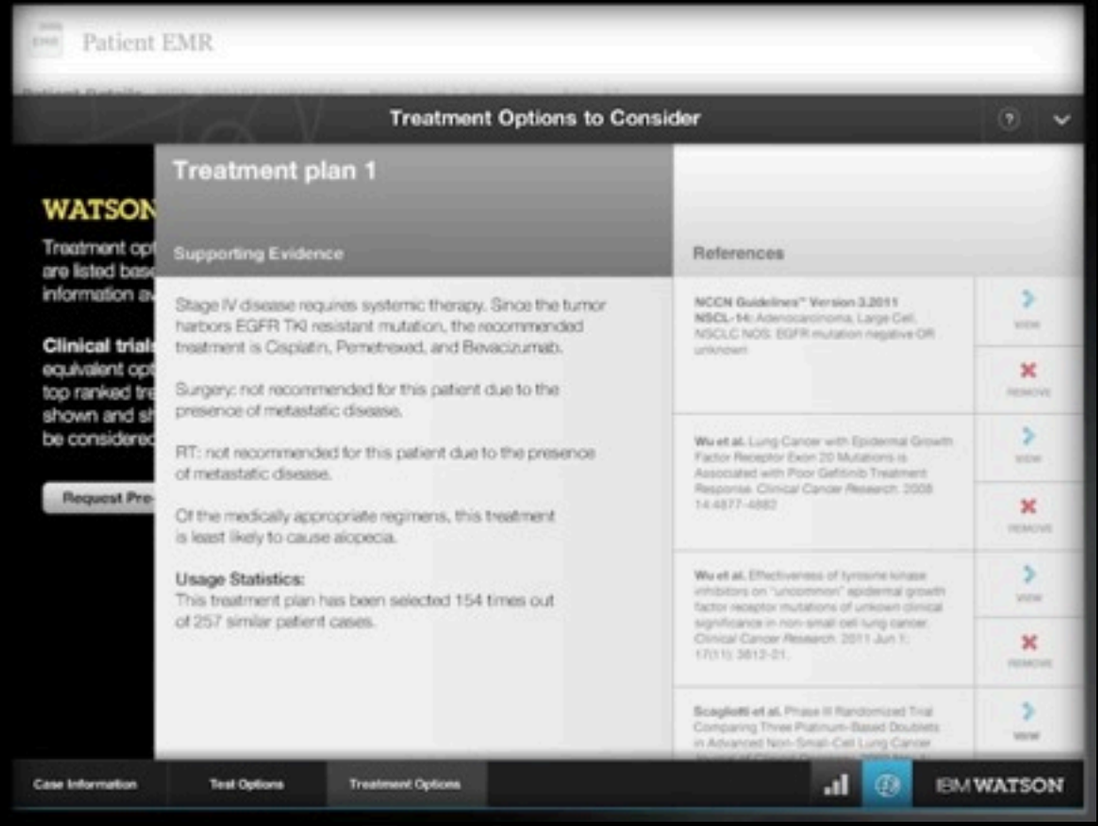


EMR

Treatment Plans



Clinical Trials



Evidences

ISSUES

컴퓨터가 인간 의사보다
더 정확하게 환자를 진료할 수 있을까?

컴퓨터가 의사보다 나은 8가지

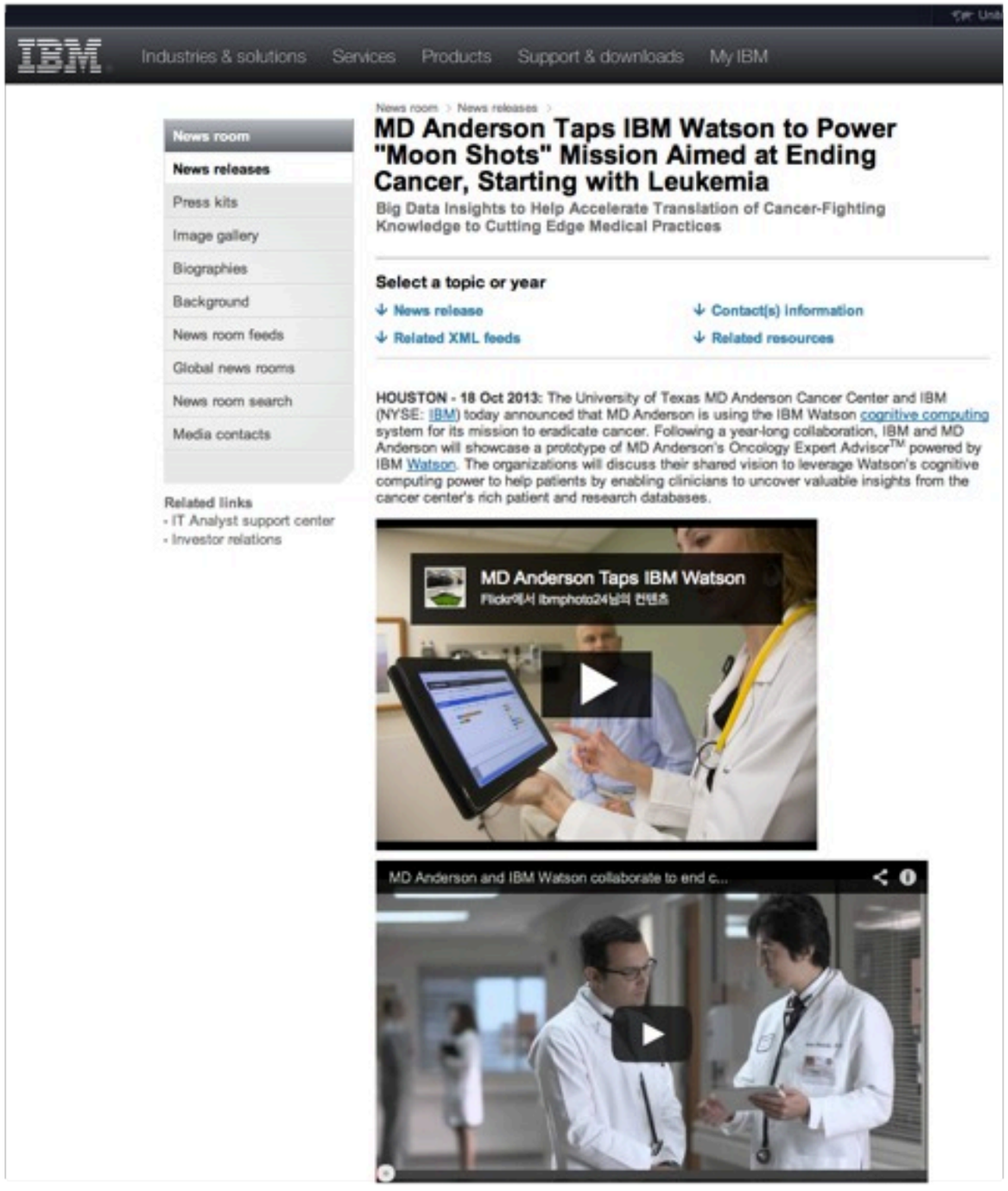
- 실시간 환자 모니터링이 가능
- 표본 데이터가 훨씬 방대함
- 데이터 처리 능력이 탁월
- 연중무휴 근무 가능
- 환자가 어디 있든 진단 가능
- 비용 및 인건비 절감
- 높은 정밀도
- 편견 없는 객관적 판단

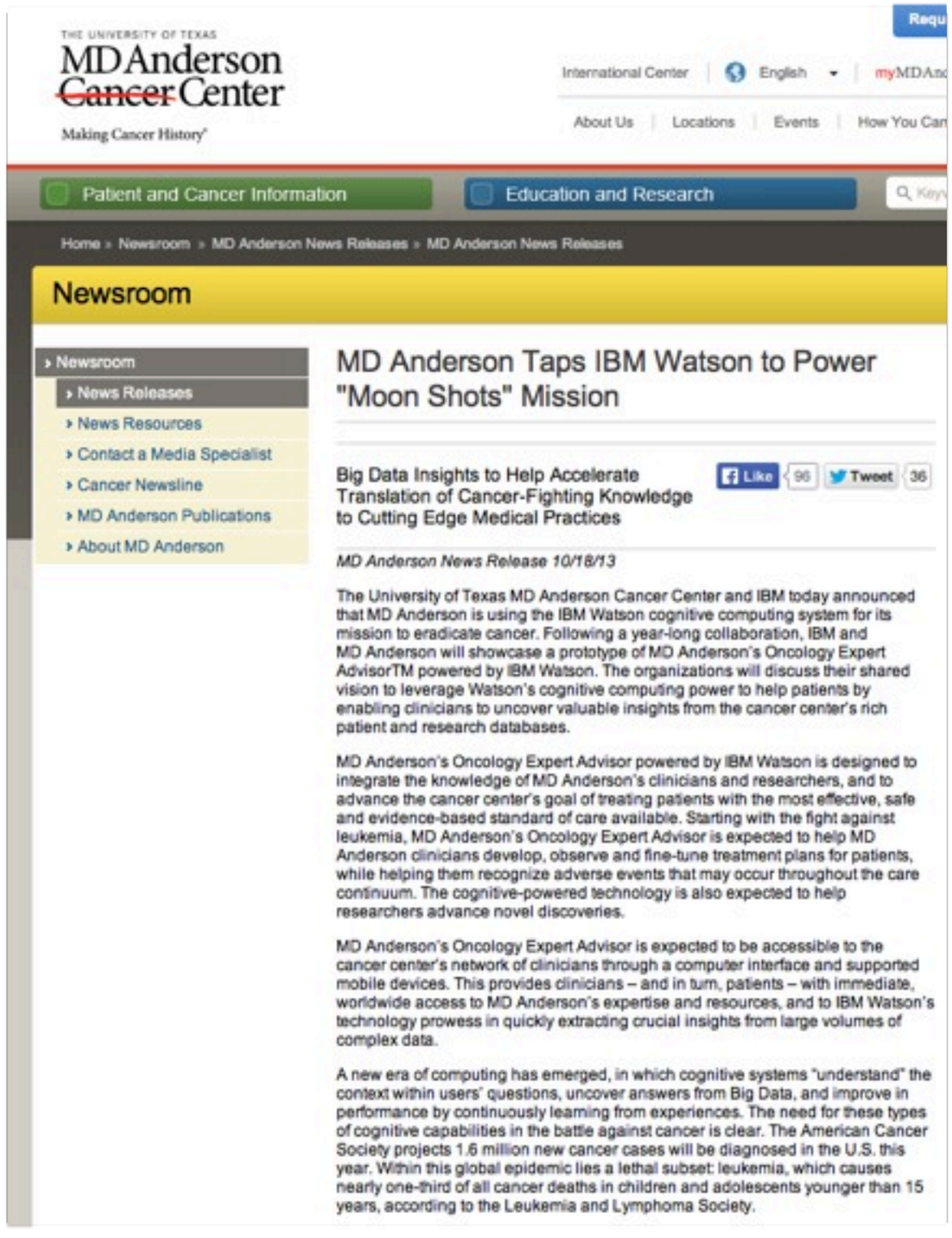
의사가 컴퓨터보다 나은 8가지

- 불의의 사고에 대한 대처 능력
- 예외적인 사례에 대한 해결
- 새로운 질병에 대한 등장
- 환자에 대한 인간적 접근
- 끊임 없는 연구의 필요성
- 컴퓨터의 관리 감독 필요
- 창의성/직감의 필요성
- 패러다임 전환에 대응

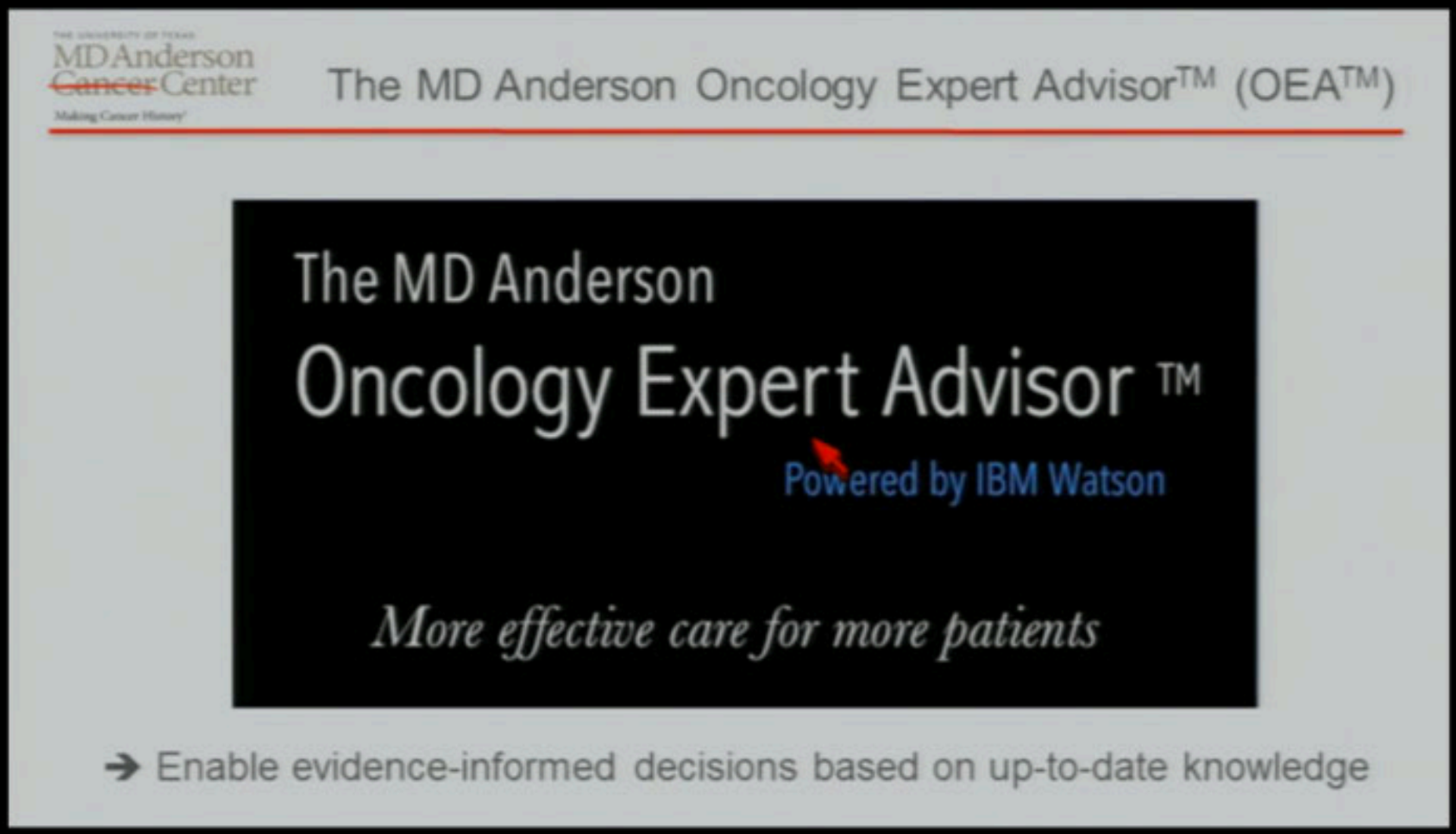
By 미래학자 토머스 프레이

MD Anderson Cancer Center





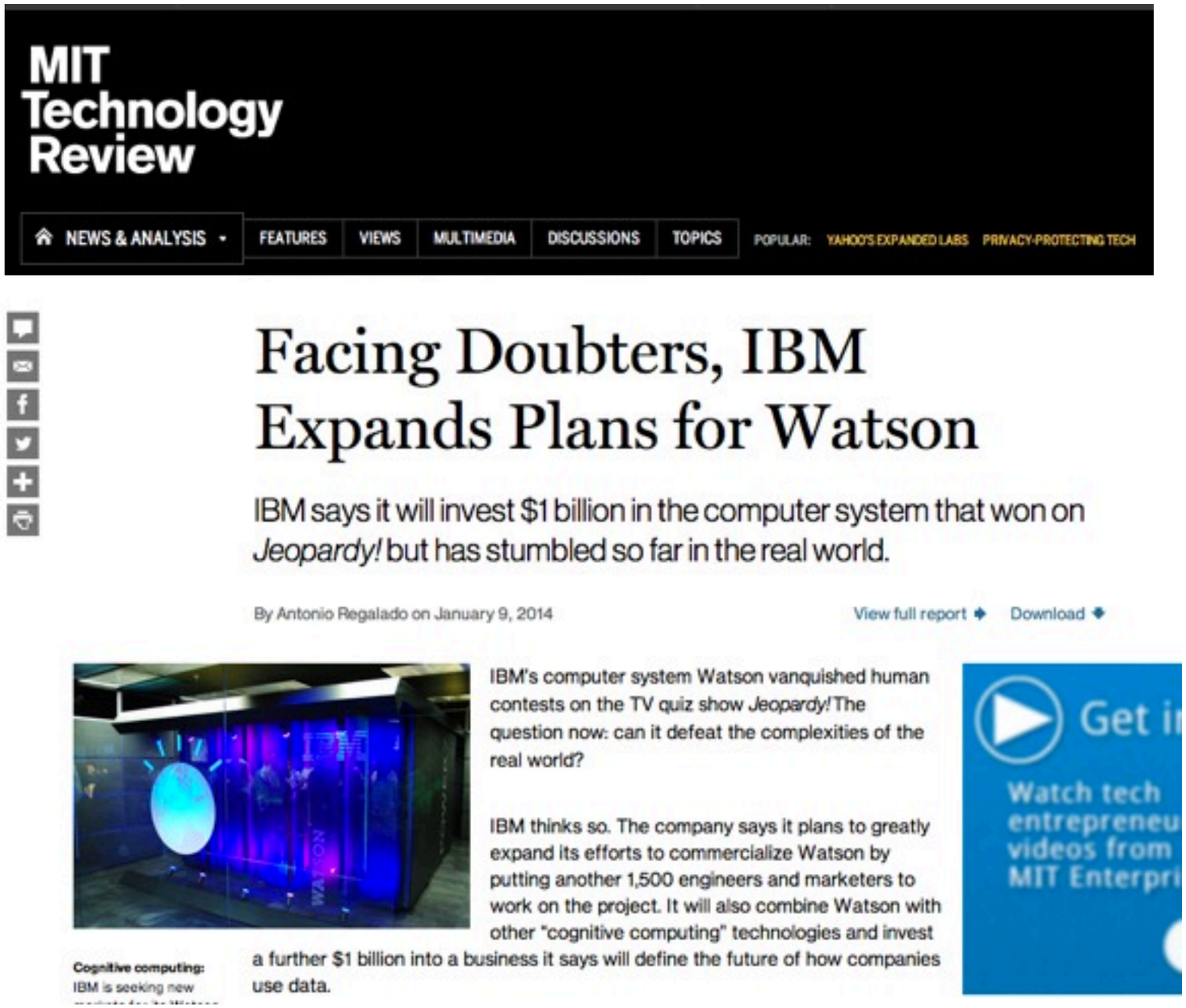
MD Anderson's Oncology Expert Advisor Powered by IBM Watson : A Web-Based Cognitive Clinical Decision Support Tool



Koichi Takahashi, MD (ASCO 2014)

MD Anderson's Oncology Expert Advisor Powered by IBM Watson : A Web-Based Cognitive Clinical Decision Support Tool

- Trained by 400 cases of historical patients cases
- Assessed accuracy OEA treatment suggestions using MD Anderson's physicians' decision as benchmark
- When 200 leukemia cases were tested,
  - False positive rate=2.9% (OEA 추천 치료법이 부정확한 경우)
  - False negative rate=0.4% (정확한 치료법이 낮은 점수를 받은 경우)
  - Overall accuracy of treatment recommendation=82.6%
- Conclusion: Suggested personalized treatment option showed reasonably high accuracy



MIT Technology Review

NEWS & ANALYSIS | FEATURES | VIEWS | MULTIMEDIA | DISCUSSIONS | TOPICS | POPULAR: YAHOO'S EXPANDED LABS | PRIVACY-PROTECTING TECH

Facing Doubters, IBM Expands Plans for Watson

IBM says it will invest $1 billion in the computer system that won on *Jeopardy!* but has stumbled so far in the real world.

By Antonio Regalado on January 9, 2014

View full report | Download

IBM's computer system Watson vanquished human contests on the TV quiz show *Jeopardy!* The question now: can it defeat the complexities of the real world?

IBM thinks so. The company says it plans to greatly expand its efforts to commercialize Watson by putting another 1,500 engineers and marketers to work on the project. It will also combine Watson with other "cognitive computing" technologies and invest a further $1 billion into a business it says will define the future of how companies use data.

Cognitive computing: IBM is seeking new

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- Watson 그룹을 독립시키고, CEO 직속 조직으로 지위 격상
- 2,000명을 투입하여 현재 인력의 5배 + $1 billion 투자
- $100 million을 투자하여 관련 어플리케이션을 만드는 벤처 생태계 조성

IBM's Watson Fund invests in health social network WellTok

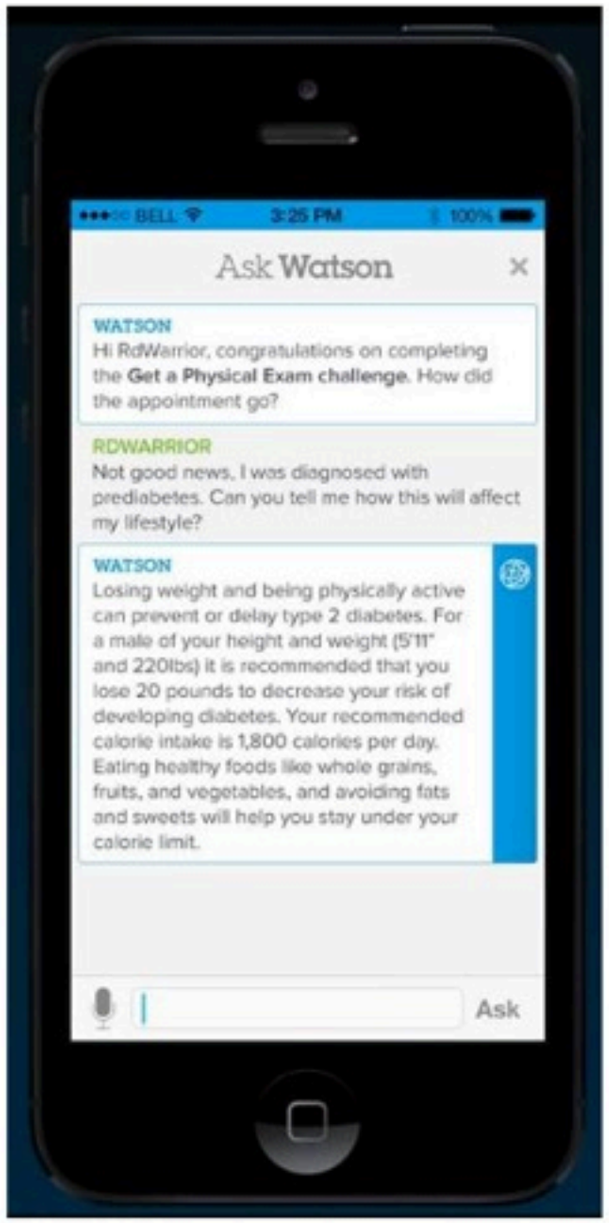
By: Brian Dolan | Feb 12, 2014

Tags: CafeWell | CafeWell Concierge | digital health investors | IBM Watson healthcare | IBM Watson medicine | MD Buyline | mobile health investors | NEA | Qualcomm Ventures | venture capital | WellTok |

Earlier this year IBM announced that it would invest $100 million into startups that integrate with Watson, its super computing platform, through a new investment fund called Watson Fund. IBM announced that it had helped contribute to health social network company WellTok's $22 million third round of funding, which was led by New Enterprise Associates and included participation from another new investor — Qualcomm Ventures. Existing investors Emergence Capital Partners, InterWest Partners, Miramar Venture Partners and Okapi Venture Capital also participated.

Last November IBM announced that WellTok would be one of the first companies to integrate Watson. WellTok incorporated Watson into its app CafeWell Concierge, for users of its existing CafeWell health social network. CafeWell is offered to consumers via population managers that include employers, health plans, and providers. CafeWell Concierge will be a premium offering for these population manager customers. By linking to existing CafeWell apps, Watson can answer users based not only on their question but also on specific information like their location, health status, health benefits, health improvement programs and incentives available from their insurer, physician or local pharmacy.

The other initial integration IBM made with Watson was in MD Buyline, which makes it another likely investment target for the new Watson Fund.



- 총 $100 million을 Watson 관련 Application을 만드는 벤처에 투자, 생태계 조성 계획
- 소셜네트워크 기반의 헬스케어 스타트업 WellTok 에 투자 ('14. 2)
- 자연어 처리에 기반,
  사용자의 질문에 답/추천 제공

http://mobihealthnews.com/29906/ibms-watson-fund-invests-in-health-social-network-welltok/

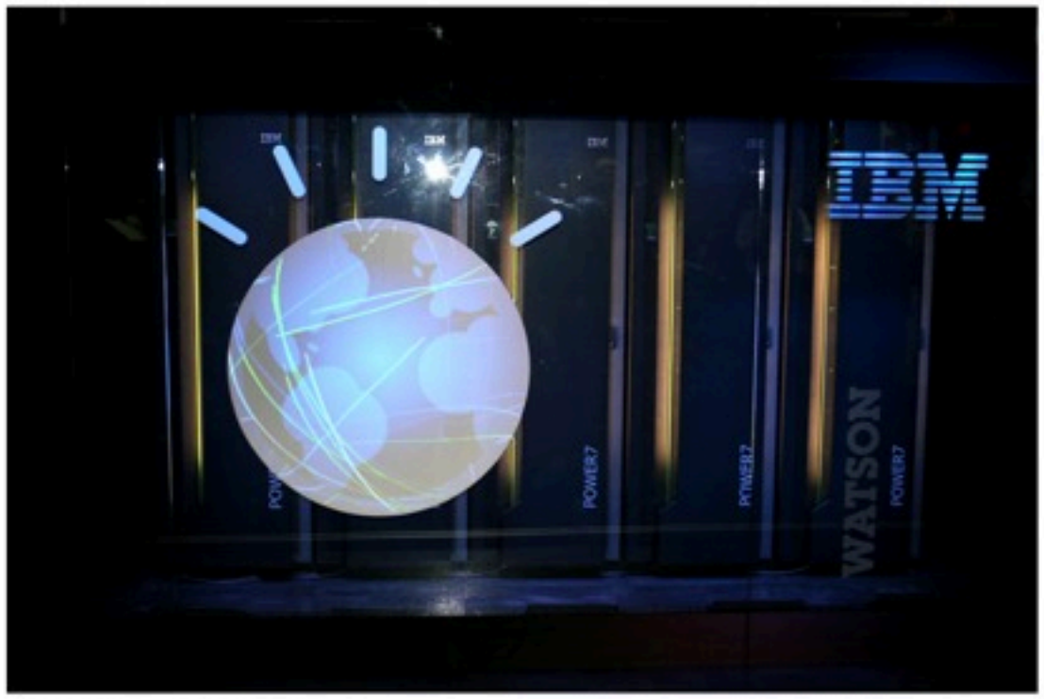
WIRED GEAR SCIENCE ENTERTAINMENT BUSINESS SECURITY DESIGN OPINION MAGAZINE

ENTERPRISE | Genomics | IBM Watson | machine learning | Pathway Genomics

IBM's Watson Supercomputer Finally Finds Its Calling: Giving You Diet Advice

BY KLINT FINLEY 11.12.14 | 11:00 AM | PERMALINK

Share 301 Tweet 798 +1 17 Share 164 Pin it



Watson. Sam Gustin/WIRED

What if you could ask your smartphone for diet and exercise advice, the same way you ask Siri for driving directions?

Biotechnology company Pathway Genomics will soon offer an app that promises to do just that. "It's meant to allow patients to be the CEO of their own health," says Pathway Genomics CEO Jim Plante. "It will provide genomic information. It will pull in the patients health records, connect to activity monitors like the Fitbit."

It will also tap into IBM Watson, the machine learning system based on the supercomputer the company used to win at TV *Jeopardy*. The Watson online service contains a wealth of information from sources such as medical text books as well as the latest medical research journals, and IBM will use this to help power the Pathway Genomics app, after investing an undisclosed amount in the startup.

Watson + Pathway Genomics

- Watson Fund 는 Pathway Genomics 에 투자
- 개인 유전 정보 및 건강 정보를 통합하고 Watson을 통해 분석 및 조언

At the Mayo Clinic, IBM Watson Takes Charge of Clinical Trials

Many clinical trials are not completed due to lack of sufficient enrollment.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Now Available for Public Comment: Notice of Proposed Rulemaking (NPRM) for FDAAA 801 and NIH Draft Reporting Policy for NIH-Funded Trials

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail Text Size

Trial record 18 of 5568 for: lung cancer
« Previous Study | Return to List | Next Study »

Improving Management of Breathlessness in Patients With Lung Cancer

This study is currently recruiting participants. (see Contacts and Locations)
Verified August 2014 by Massachusetts General Hospital

Sponsor:
Massachusetts General Hospital

Information provided by (Responsible Party):
Joseph A. Greer, Ph.D., Massachusetts General Hospital

ClinicalTrials.gov Identifier:
NCT01937637

First received: August 27, 2013
Last updated: August 15, 2014
Last verified: August 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Many individuals with **lung cancer** experience debilitating breathlessness at some point during the course of their illness. Unfortunately, few interventions exist to treat this distressing symptom of **cancer**.

In this study, the investigators plan on recruiting individuals with **lung cancer** to participate in a behavioral intervention to help relieve breathlessness. The principal investigator of the study, Dr. Joseph Greer, is a licensed clinical psychologist who has trained nurse practitioners in how to deliver the behavioral intervention. The nurse practitioners will meet with patients diagnosed with **lung cancer** during their outpatient oncology appointments, such as chemotherapy infusions, to review the behavioral skills that may help with breathlessness. Specifically, the intervention includes education about the relationship between breathlessness and the stress response as well as teaches patients skills for breathing control and relaxation of the body.

For this single-group pilot study, the investigators will ask participants to provide feedback about whether they found the intervention acceptable and effective. Participants will also complete questionnaires about their physical and psychological symptoms before and after the intervention in order to measure its effectiveness for treating breathlessness and any distress related to breathlessness. The data from this study will help inform improvements to the intervention in order to make it feasible and effective for treating breathlessness in patients with **lung cancer**.

Condition	Intervention
Breathlessness Dyspnea **Lung Cancer**	Behavioral: Cognitive Behavioral Intervention for Breathlessness

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Supportive Care

Official Title: Improving Management of Breathlessness in Patients With **Lung Cancer**

Resource links provided by NLM:

MedlinePlus related topics: Breathing Problems Cancer Lung Cancer

U.S. FDA Resources

- Effect of a nurse practitioner-delivered dyspnea management intervention on mood symptoms in patients with advanced **lung cancer** [Time Frame: 1) Pre-intervention (after enrollment); and 2) Post-intervention (within two weeks of completing the intervention)] [Designated as safety issue: No]

  Hospital Anxiety and Depression Scale (HADS): The 14-item HADS will serve as another secondary outcome, consisting of two subscales that screen for symptoms of anxiety and depression in the past week.

Estimated Enrollment: 35
Study Start Date: July 2013
Estimated Study Completion Date: December 2014
Estimated Primary Completion Date: October 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Behavioral Intervention for Dyspnea In the first intervention session, enrolled participants will learn breathing and relaxation exercises designed to relieve breathlessness. The nurse practitioner will also provide handouts with directions for these exercises, an audio-recording with the relaxation exercises, and worksheets for daily home practice. During the second session, participants will again meet with the nurse practitioner to review the study exercises and to address any difficulties participants may have experienced in practicing the skills. All participants will complete questionnaires before and after the study intervention as well as a brief follow-up interview with the research assistant to obtain feedback about ways to improve the intervention to relieve breathlessness in patients with **lung cancer**.	Behavioral: Cognitive Behavioral Intervention for Breathlessness Cognitive behavioral intervention for breathlessness, delivered by nurse practitioners during outpatient oncology appointments, in up to 8 patients with advanced **lung cancer**. Other Name: Dyspnea Intervention

Detailed Description:
The purpose of this single-group pilot study is to test the feasibility and acceptability of a cognitive-behavioral intervention for breathlessness in patients with lung cancer. Clinic staff and research assistants will recruit potential participants in the outpatient oncology department of the Massachusetts General Hospital. All participants will complete informed consent procedures prior to initiating the study. The Dana-Farber/Partners Institutional Review Board has approved the study methods.

Before beginning the first intervention session, enrolled participants will complete questionnaires either on paper or online via a secure survey website. The questionnaire takes about 15 minutes to complete and asks about the experience of breathlessness, mood and anxiety symptoms, as well as general quality-of-life. Participants may refuse to answer any questions that they do not wish to answer.

The study intervention involves two sessions with a nurse practitioner. Each session will take approximately 30-45 minutes to complete.

- The first session will be scheduled around another oncology appointment, such immediately before or after a clinic visit, or at the same time as a chemotherapy infusion. During this session, participants will learn about several breathing and relaxation exercises designed to relieve breathlessness. The nurse practitioner will also provide handouts with directions for these exercises, an audio recording of the relaxation techniques, and worksheets to encourage daily practice of these breathing and relaxation exercises at home.
- The second session, which will take place 1-4 weeks after the first session, may also be scheduled either before or after another oncology appointment. However, if this is not possible, the second session may be completed over the telephone. During this session, participants will meet with the same nurse practitioner to review the behavioral exercises and to address any difficulties the participants may have experienced in practicing the exercises.

Within two weeks after the second intervention session, a research assistant will contact the participants either in person or over the telephone to complete the same questionnaires administered before the intervention. Participants may choose to complete the follow-up questionnaires on paper, over the telephone, or on a secure internet survey website. Also, within two weeks after the second intervention session, the research assistant will conduct a brief interview with the participants. Specifically, the research assistant will ask questions about participants' perceived satisfaction with the behavioral intervention and obtain feedback about how to improve the intervention. The interview will be audio-recorded and take approximately 15-20 minutes to complete. These recordings and transcripts will only be identified with a study number and stored electronically in a computer file that is protected with a password only accessible to study staff. After completing the interview, participants will be finished with the study.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Clinical diagnosis of stage III and IV non-small cell lung cancer (NSCLC) or extensive stage small-cell lung cancer (SCLC)
- Must be an adult (age greater than 18 years)
- Must receive cancer treatment (radiation or chemotherapy) within the ambulatory clinics of the Massachusetts General Hospital Cancer
- Must have an Eastern Cooperative Oncology Performance Status ranging from 0 (asymptomatic) to 2 (symptomatic but in bed less than 50% of time)
- Must have moderate breathlessness (i.e., a score of 2 or greater) on the Modified Medical Research Council Dyspnea Scale

Exclusion Criteria:

- Any untreated major mental illness or neuropsychiatric deficit prohibiting informed consent and/or ability to complete study procedures.

- Clinical trial information is unstructured big data.
- Matching eligible patients with trials is a matter of luck and guesswork.

At the Mayo Clinic,
IBM Watson Takes Charge of Clinical Trials

- Currently, matching eligible patients with trials is a matter of luck and guesswork.
  - Even at Mayo Clinic, just 5% of patients take part in studies.
  - Nationally, the rate is even lower, at 3%.
- Mayo hopes to raise clinical trial involvement to include up to 10% of its patients, through collaboration with Watson.

Wearable Healthcare Devices

웨어러블 디바이스

GLASS

Google Glass How-to: Getting Started

세르게이 브린의 pet project로 시작한 google glass

- 구글 글래스가 실제로는 얼마나 쓸모가 있을지에 대한 의문
- 스마트폰만으로는 불가능한, 구글 글래스만의 기능은?
- Killer application을 개발하는 것이 가장 중요할 것

회의론자들 조차도 의료 분야에서는
구글 글래스의 활용을 긍정적으로 바라봄

#ifihadglass project

2013년 2월 1000명의 지원자들을 선정하여 베타테스터, 'Google Glass Explorer' 로 선정

3 out of 5 Glass Certified Partners by Glass at Work develop applications in medicine/healthcare

Glass at Work

Glass Certified Partners are authorized by Glass at Work for delivering enterprise solutions for Glass. They are also eligible for co-branding and listing on the Glass at Work website.

If you are a developer interested in becoming a Glass Certified Partner or if you are an enterprise looking to stay informed about Glass at Work, please let us know.

Glass Certified Partners

APX LABS

APX Labs makes Skylight, the leading business software for Glass. It provides workers with hands-free, real-time access to enterprise data and the expertise they need to do their job. Skylight is used by Fortune 500 companies spanning multiple industries
Contact APX Labs

AUGMEDIX

Doctors spend over a third of their day pushing and pulling information to and from the Electronic Health Record. Augmedix provides a service for doctors that allows them to reclaim this time and refocus it on what matters most: patient care.
Contact Augmedix

CrowdOptic

CrowdOptic's software detects significant broadcast events from mobile and wearable devices, and provides breathtaking content for live broadcasts and context-aware applications for the sports, entertainment, building/security, and medical industries.
Contact Crowd Optic

GuidiGO
Every place has a story to tell

Our mission is to inspire people to connect with art and culture through a compelling mobile storytelling experience. Glass brings us closer to that vision, and by partnering with museums and cultural institutions this becomes accessible to everyone.
Contact GuidiGo

wearable intelligence

Wearable Intelligence creates Glassware for energy, manufacturing, healthcare, and more. Our workflow, communications, training, and data access products are in the field at some of the world's best known companies.
Contact Wearable Intelligence

Jun 16. 2014

- 수술 중 영상데이터 참고
- 수술 중 의견 교환
- 진료 기록 저장 및 공유
- 오지 및 전시 의료
- 엠뷸런스 내 응급환자
- 의과 대학생 교육용

VitalMedicals

smart hospital technologies

Introducing

The Connected Surgeon

수술에 구글 글래스를 활용한 의사들 I

Eastern Maine Medical Center의 Rafael J. Grossmann

- 내장에 관을 삽입하는 경피내시경 위루조성술 (PEG)이라는 비교적 일상적인 수술을 수행
- 구글 글래스로 수술의 전 과정을 자신의 아이패드에 원격으로 접속하여 생중계 및 녹화

수술에 구글 글래스를 활용한 의사들 II

UCSF Medical Center 의 흉부외과 전문의 Pierre Theodore

- 환자의 CT 스캔 이미지를 구글 글래스를 통해 확인하면서 수술을 진행
- 환자와 영상 검사 결과를 번갈아 보는 것이 수술에 "엄청난 도움이 되었다 (extraordinary helpful)"
- "운전을 할 때, 잠깐씩 백미러를 보는 것에 문제가 없는 것과 같다"

수술에 구글 글래스를 활용한 의사들 III

Ohio State University Wexner Medical Center의 Dr. Christopher Ceding

- 글래스를 통해 이 수술은 도시의 반대편에 위치한 동료의사에게 중계
- Ohio State University 의과대학 학생들에게도 생중계되어, 랩탑으로 수술을 실시간 견학

수술에 구글 글래스를 활용한 의사들 III

- 글래스를 통해 이 수술은 도시의 반대편에 위치한 동료의사에게 중계
- Ohio State University 의과대학 학생들에게도 생중계되어, 랩탑으로 수술을 실시간 견학

수술에 구글 글래스를 활용한 의사들 III

Ohio State University Wexner Medical Center의 Dr. Christopher Ceding

"솔직히, 수술에 들어간 후에는 내가 글래스를 쓰고 있다는 것조차 잊어버렸다.
글래스는 아주 직관적이며, 착용하지 않은 것과 다름 없을 정도로 편리하다."

Rhode Island Hospital Launches Country's First Google Glass Study in Emergency Department Setting

Rhode Island Hospital Launches Country's First Google Glass Study in Emergency Department Setting

3/7/2014

Study to explore efficacy of real-time consults using streaming mobile technology

Rhode Island Hospital is bringing **Google Glass** into the emergency department. Using a stripped-down version of the wearable mobile video communications technology, researchers will test the efficacy of using Google Glass for real-time audio-visual consults for consented patients who require a dermatology consultation. Rhode Island Hospital is the first hospital in the U.S. to use Google Glass in an emergency department setting.

Paul Porter, MD, a physician in the Rhode Island Hospital department of emergency medicine, explains a feasibility study using a stripped-down, HIPAA-compliant version of Google Glass to provide patients with an audio-visual dermatological consultation in real time.

"We live in a world of instant gratification, and in many ways, we're testing that mindset by using Google Glass to enhance telemedicine in the emergency department," said principal investigator Paul Porter, M.D., a physician in the emergency departments of Rhode Island, Hasbro Children's and The Miriam hospitals. "In this study, we will use Google Glass to stream live images of a patient's dermatological condition to the consulting dermatologist. As the emergency medicine physician observes the patient's skin condition, the consulting dermatologist will be able to see identical images on a tablet in real time, giving the dermatologist the ability to offer appropriate advice, diagnosis and treatment options."

Porter and researchers Peter Chai, M.D., and Roger Wu, M.D., worked with experts at **Pristine**, a health care technology communications company, which has developed the only form of Google Glass that meets strict federal patient privacy laws (Health Insurance

"In this study, we will use Google Glass to stream live images of a patient's dermatological condition to the consulting dermatologist. As the emergency medicine physician observes the patient's skin condition, the consulting dermatologist will be able to see identical images on a tablet in real time, giving the dermatologist the ability to offer appropriate advice, diagnosis and treatment options."

- Paul Porter, MD

2014.3

Beth Israel to use Google Glass throughout emergency room

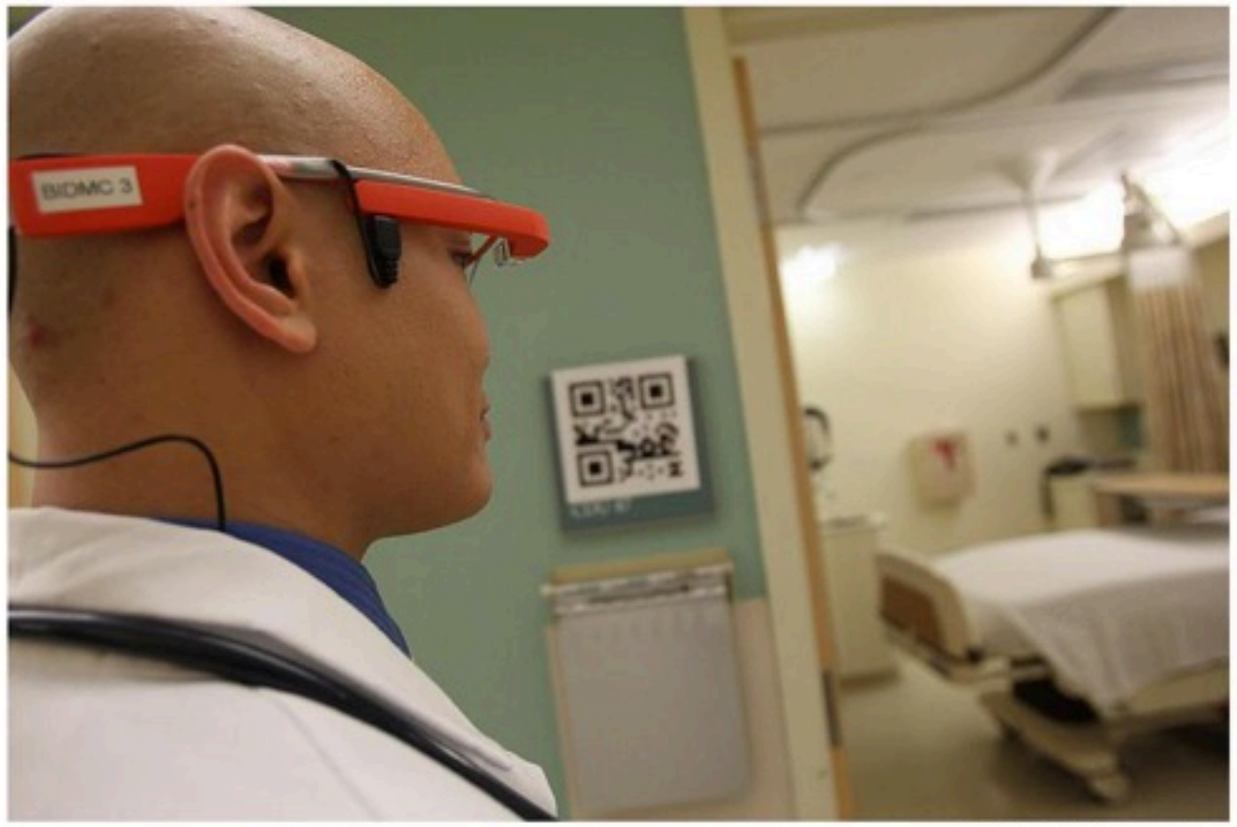
2014. 4.

Google Glass embraced at Beth Israel Deaconess

Wearable screens a part of everyday medical care

By Callum Borchers | GLOBE STAFF APRIL 09, 2014

ARTICLE COMMENTS (6)



SUZANNE KREITER/GLOBE STAFF

Dr. Steven Horng shows Google Glass that he and other doctors will use to read patient records.

PRINT REPRINTS E-MAIL SHARE

Dr. Steven Horng launched a Google Glass pilot program at Beth Israel Deaconess Medical Center late last year because he thought the futuristic device could help save lives. One night in January proved that.

Beth Israel Deaconess is expanding the use of Google Glass to its entire emergency department, and the hospital said it is the first in the United States to employ the device for everyday medical care.

Before entering the room, the Beth Israel doctor can scan the QR code with his Glass, and the patient's information is promptly displayed on the screen.

UC Irvine School of Medicine first to integrate Google Glass into curriculum

2014. 4.

Steve Zylius/UC Irvine

Dr. Warren Wiechmann, assistant clinical professor of emergency medicine and associate dean of instructional technologies, will oversee implementation of the Google Glass four-year program at UCI. Download image

UCI School of Medicine first to integrate Google Glass into curriculum

Wearable computing technology will transform training of future doctors

Irvine, Calif., May 14, 2014 — As physicians and surgeons explore how to use Google Glass, the UC Irvine School of Medicine is taking steps to become the first in the nation to integrate the wearable computer into its four-year curriculum – from first- and second-year anatomy courses and clinical skills training to third- and fourth-year hospital rotations.

Leaders of the medical school have confidence that faculty and students will benefit from Glass's

UC Irvine School of Medicine is taking steps to become the first in the nation to integrate the wearable computer into its four-year curriculum – from first- and second-year anatomy courses and clinical skills training to third- and fourth-year hospital rotations.

Google Glass enters operating room at Stanford

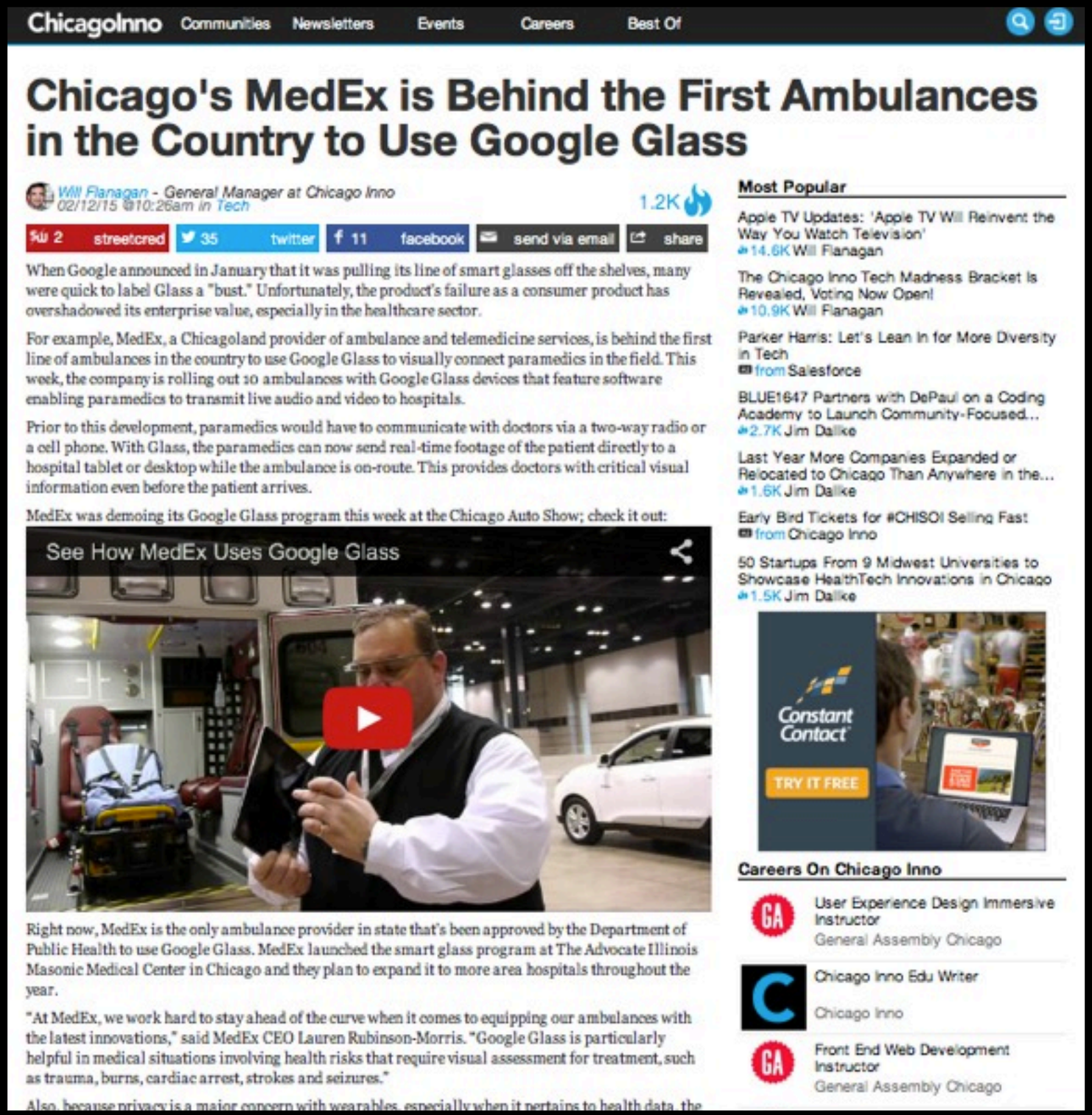
2014. 7.

Stanford University Medical Center's Department of Cardiothoracic Surgery has started using Google Glass in its resident training program.

While a resident is operating on a patient, surgeons can use the CrowdOptic software to watch the resident's progress and send visual feedback to the resident on technique.

Chicago's MedEx is Behind the First Ambulances in the Country to Use Google Glass

2015. 2.



ChicagoInno Communities Newsletters Events Careers Best Of

Chicago's MedEx is Behind the First Ambulances in the Country to Use Google Glass

Will Flanagan - General Manager at Chicago Inno
02/12/15 @10:26am in Tech

1.2K

2 streetcred | 35 twitter | 11 facebook | send via email | share

When Google announced in January that it was pulling its line of smart glasses off the shelves, many were quick to label Glass a "bust." Unfortunately, the product's failure as a consumer product has overshadowed its enterprise value, especially in the healthcare sector.

For example, MedEx, a Chicagoland provider of ambulance and telemedicine services, is behind the first line of ambulances in the country to use Google Glass to visually connect paramedics in the field. This week, the company is rolling out 10 ambulances with Google Glass devices that feature software enabling paramedics to transmit live audio and video to hospitals.

Prior to this development, paramedics would have to communicate with doctors via a two-way radio or a cell phone. With Glass, the paramedics can now send real-time footage of the patient directly to a hospital tablet or desktop while the ambulance is on-route. This provides doctors with critical visual information even before the patient arrives.

MedEx was demoing its Google Glass program this week at the Chicago Auto Show; check it out:

Right now, MedEx is the only ambulance provider in state that's been approved by the Department of Public Health to use Google Glass. MedEx launched the smart glass program at The Advocate Illinois Masonic Medical Center in Chicago and they plan to expand it to more area hospitals throughout the year.

"At MedEx, we work hard to stay ahead of the curve when it comes to equipping our ambulances with the latest innovations," said MedEx CEO Lauren Rubinson-Morris. "Google Glass is particularly helpful in medical situations involving health risks that require visual assessment for treatment, such as trauma, burns, cardiac arrest, strokes and seizures."

Also, because privacy is a major concern with wearables, especially when it pertains to health data, the

Most Popular

Apple TV Updates: 'Apple TV Will Reinvent the Way You Watch Television'
14.6K Will Flanagan

The Chicago Inno Tech Madness Bracket Is Revealed, Voting Now Open!
10.9K Will Flanagan

Parker Harris: Let's Lean In for More Diversity in Tech
from Salesforce

BLUE1647 Partners with DePaul on a Coding Academy to Launch Community-Focused...
2.7K Jim Dalke

Last Year More Companies Expanded or Relocated to Chicago Than Anywhere in the...
1.6K Jim Dalke

Early Bird Tickets for #CHISOI Selling Fast
from Chicago Inno

50 Startups From 9 Midwest Universities to Showcase HealthTech Innovations in Chicago
1.5K Jim Dalke

Careers On Chicago Inno

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General Assembly Chicago

Chicago Inno Edu Writer
Chicago Inno

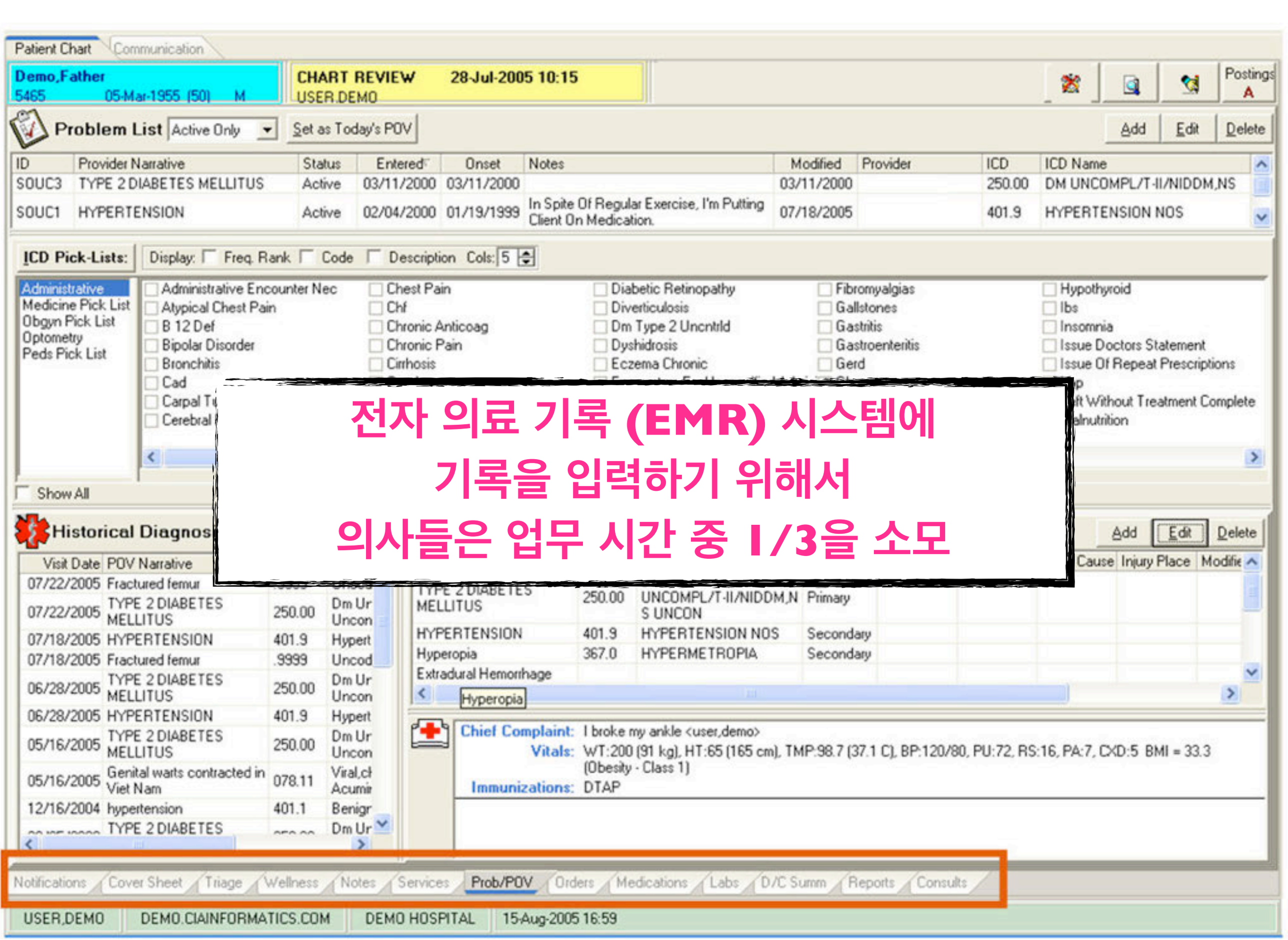
Front End Web Development Instructor
General Assembly Chicago

MedEx, a Chicagoland provider of ambulance and telemedicine services, is behind the first line of ambulances in the country to use Google Glass to visually connect paramedics in the field. This week, the company is rolling out 10 ambulances with Google Glass devices that feature software enabling paramedics to transmit live audio and video to hospitals.

AUGMEDIX

Rehumanizing Health Care

“어디가 아프세요?”



전자 의료 기록 (EMR) 시스템에 기록을 입력하기 위해서 의사들은 업무 시간 중 1/3을 소모

"re-humanize the doctor/patient interaction"

AUGMEDIX

2 patients ready

"Augmedix"

4

Richard Stevens
58, M

high blood pressure, cholesterol, needs medication adjustment

golfer

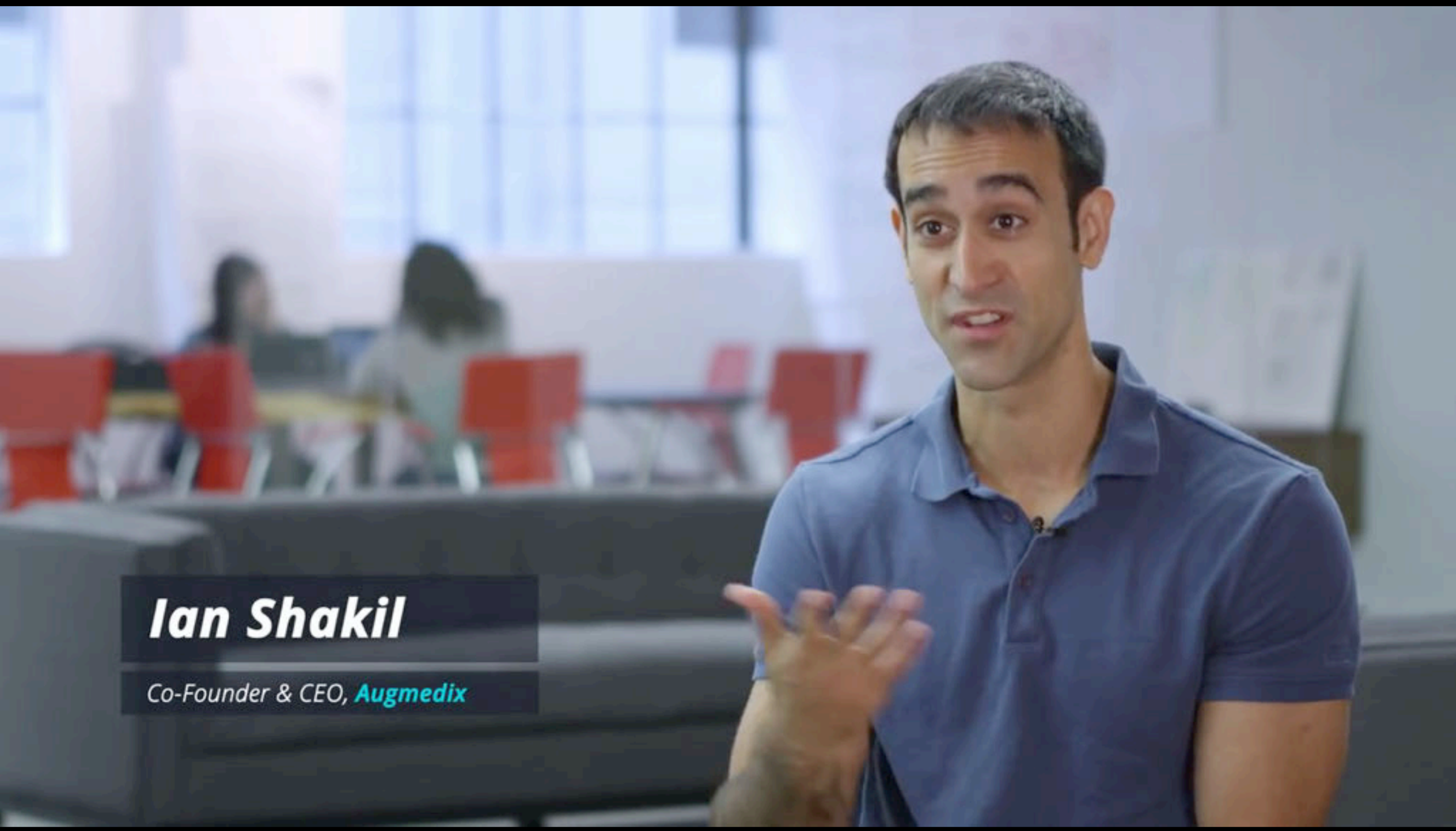
214 lbs.
weight

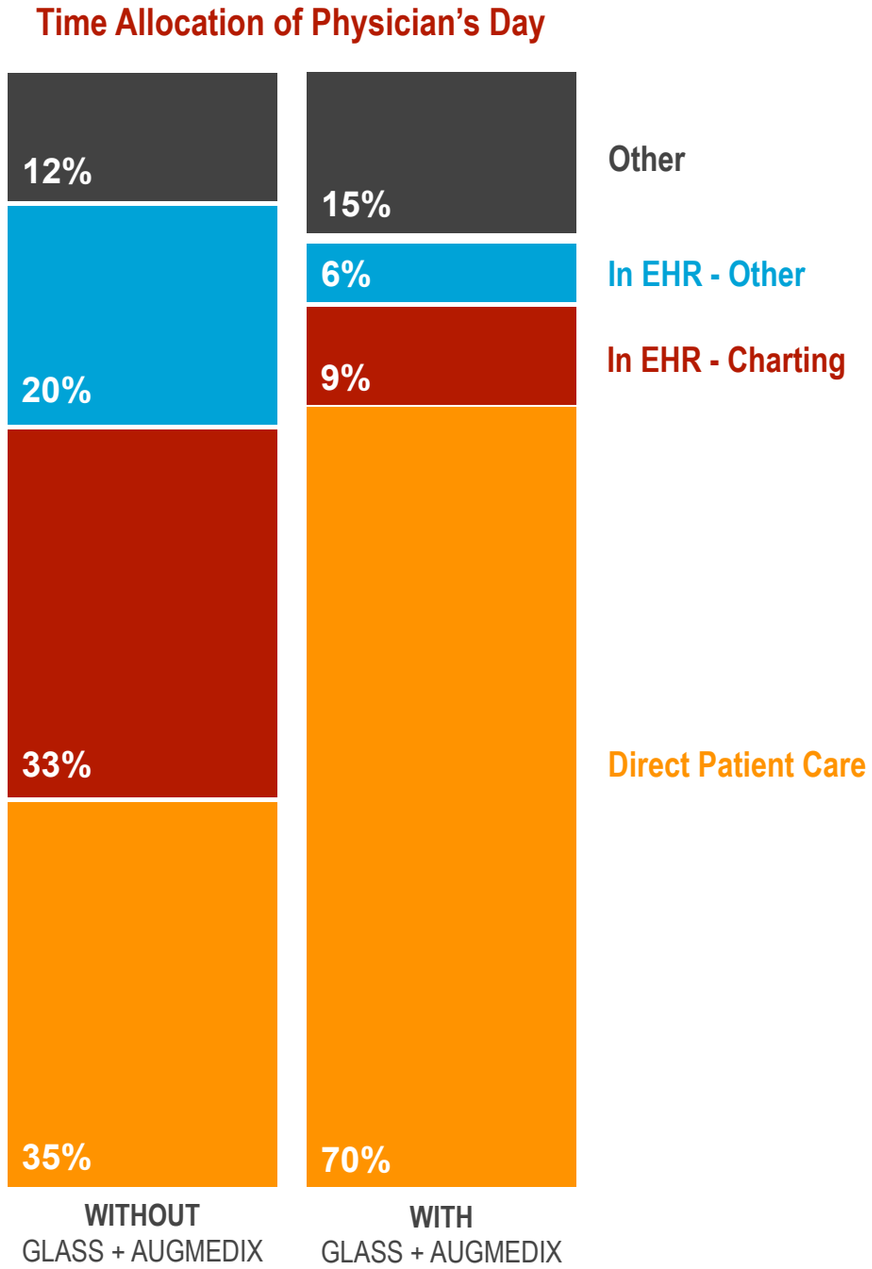
120/90
blood pressure

98.5°
temperature

180/bmp
pulse

Augmedix + Myo: Redefining Patient-physician Interactions

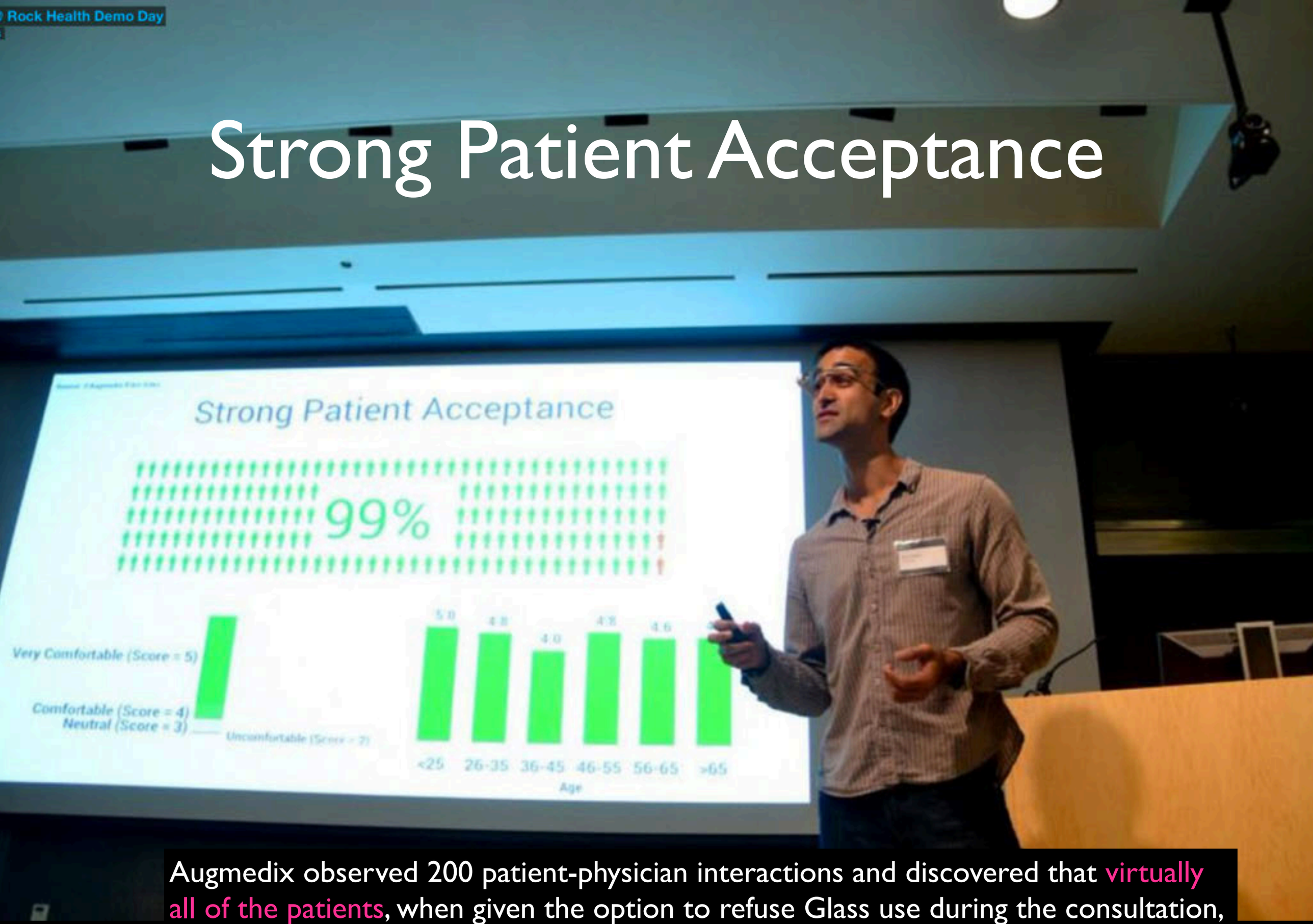




- 캘리포니아 Ventura Medical Clinic에서 임상연구
- 2014년 1월부터 2,700 건의 환자 진료에 적용
- EMR 데이터 입력 시간: 총 근무 시간의 53% → 15%
- 환자와 대면하는 시간: 총 근무 시간의 35% → 70%

http://www.dignityhealth.org/Video/GLASS

Strong Patient Acceptance



Augmedix observed 200 patient-physician interactions and discovered that virtually all of the patients, when given the option to refuse Glass use during the consultation, opted to allow the physician to wear the device.

열심히 처방해주면 뭐하겠냐...

MEDICATION ADHERENCE PROBLEM

"환자들 중 최소 절반은 처방대로 약을 복용하지 않는다"

- World Health Organization-

"처방을 따르지 않는 것 때문에 연간 $290 billion 의 의료 비용이 낭비.
연간 3.5 million 번의 입원과 125,000 명의 사망을 초래"

- New England Healthcare Institute -

WHY

1. 잊어버려서 (esp. 만성질환 환자, 고령 환자)
2. 심리적인 이유: '이만하면 다 나은 것 같은데?' / 부작용에 대한 불안
3. 금전적인 이유

어떻게 해야 환자들이
처방대로 약을 잘 복용할까?

Smart Phone App

(J&J Care4Today)

Smart Pill Cap

(Vitality's GlowCap)

Smart Pill Box

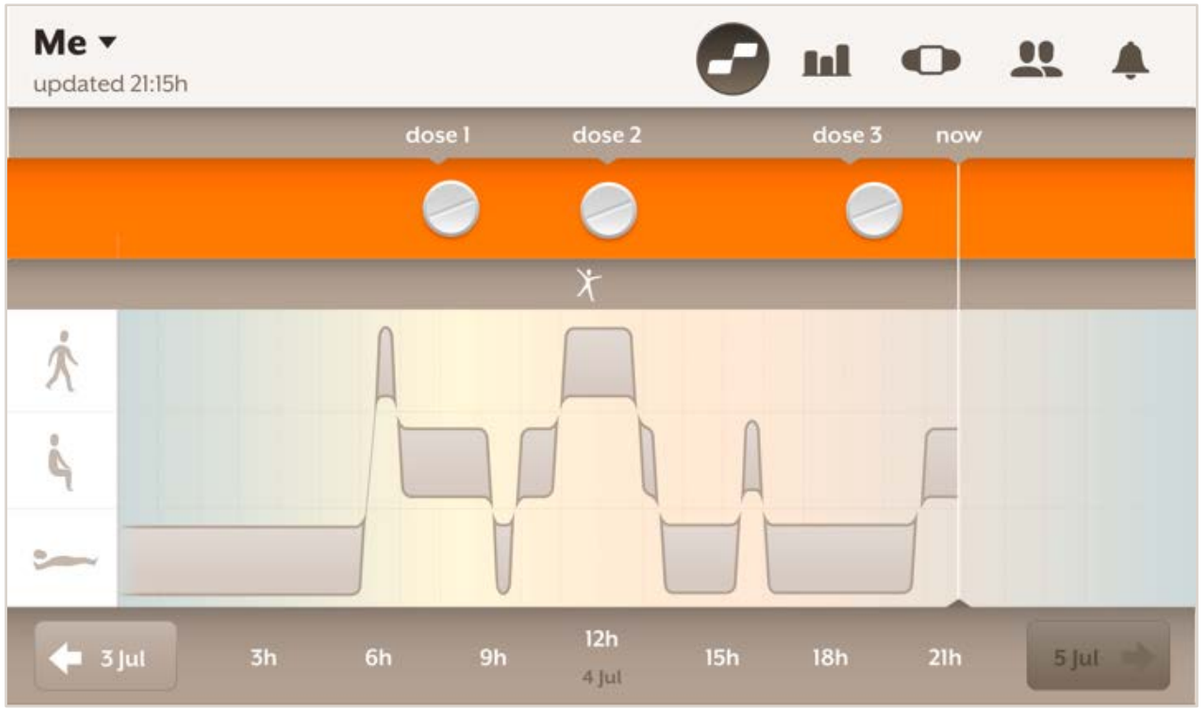
(MedMinder's Pill Dispenser)

약을 정말 복용하는지, 혹은 그냥 버리는지
여부는 알 수 없다.

약에 추적 센서를 달아서
환자가 제대로 복용하는지를 알 수 있다면?

PROTEUS
Digital Health

- 소화 가능한 센서 (Ingestible Sensor), a.k.a. '스마트 필 (Smart Pill)'
- 모래알 크기의 센서로, 무기질인 '구리'와 '마그네슘'으로 구성
- 약에 달아서 복용한 후, 위액과 반응하면 1.5 볼트의 미세 전류 발생
    - '레몬 전지' 의 원리 (Powered by You!)
    - 이후 센서는 자연스럽게 소화됨
- 이 전류를 패치로 감지하여, 스마트폰/클라우드 등에 기록으로 남김
    - 실제 약을 복용했을 때만 기록이 남음
- 2012년 7월 FDA 승인, 2010년 유럽 CE 마크 획득



A personal info stream

A ribbon with activity and medication shows daily patterns, so conversations can move beyond health tactics.

Nudges that know you

Customizable notifications are smart – based on real-time data and usual patterns.

Insights into trends

Longitudinal charts identify trends early and can easily be sent to caregivers or clinicians.

An Ingestible Sensor for Measuring Medication Adherence

Exposure and performance in clinical trials

412 subjects	99.1% Detection accuracy
20,993 ingestions	100% Correct identification
Maximum daily ingestion: 34	0% False positives
Maximum use days: 90 days	No SAEs / UADEs related to system

Trials were conducted in the following patient populations. The number of patients in each study is indicated in parentheses: Healthy Volunteers (296), Cardiovascular disease (53), Tuberculosis (30), Psychiatry (28).
SAE = Serious Adverse Event; UADE = Unanticipated Adverse Device Effect)

IEEE Trans Biomed Eng. 2014 Jul

- FastCompany 선정 2013년 가장 혁신적인 회사 34위
- 다국적 제약사들, 특히 노바티스에서 큰 관심을 보이고 있음
    - 2010년 장기이식 거부반응 약에 사용할 권리를 $24m 에 라이센싱
- 의사 처방대로 약을 잘 복용하는 것이 특히 중요한 질병에 우선 적용
    - 심혈관 계통 질환, 중추 신경계 질환 (알츠하이머, 헌팅턴 …), 장기이식 거부반응 etc

무엇이 가능해질까?

- **환자**: 더욱 효율적으로 치료 받을 수 있음
  - 복용 정보를 자신, 주치의, 보호자 등과 정보 공유 가능
  - 잊지 않고 처방에 따른 복용 가능
- **의사**: 환자를 더욱 효과적으로 치료 가능
  - 환자의 더딘 호전이, 약의 효능 때문인지, 약을 제대로 복용하지 않기 때문인지 판단 가능
- **제약회사**
  - 임상 시험 참가자 관리 및 데이터 신뢰 여부를 따질 수 있음
  - 피실험자의 재택 임상 시험도 좀 더 용이해짐
- **의료보험사**: 처방을 따르지 않는 환자에게 보험상의 불이익 가능

"Virtual" Clinical Trial Allowing Patients to Participate Regardless Of Geography

News & Media

- Press Releases
  - Press Release Archive
  - Press Statements Archive
- Featured Stories
- Video Gallery
- Frequently Requested Info
- Press Kits
- Download Multimedia
- Social Media
- Contact Pfizer Media Relations

Pfizer Conducts First "Virtual" Clinical Trial Allowing Patients to Participate Regardless Of Geography

Pilot Study Will Compare Results to Previous Trial Data to Assess Validity of New Approach

Tuesday, June 7, 2011 3:00 pm EDT

Dateline:
NEW YORK

Public Company Information:
NYSE: PFE
US7170811035

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. announced today that it is conducting the first-ever randomized clinical trial under an investigational new drug (IND) application that manages study participation entirely using electronic tools and allows patients to participate in the clinical trial regardless of their proximity to clinical sites. The pilot project, initiated following review from the U.S. Food and Drug Administration (FDA), uses mobile phone and web-based technology to collect necessary data for the trial without clinic visits.

"This virtual method enables scientists to conduct trials more efficiently. Additionally, as more people participate in trials conveniently from home, the results of trials may apply to a broader patient population"

The Research on Electronic Monitoring of OAB Treatment Experience – REMOTE – is a U.S.-based Participatory Patient-Centered (PPC) clinical trial designed to assess the safety and efficacy of Detrol LA (tolterodine tartrate), a treatment for overactive bladder (OAB). Pfizer and its research partners hope to determine whether the results of the pilot REMOTE "virtual trial" can replicate the results of a previously completed Phase IV Detrol LA trial, and in this way begin to validate virtual, patient-centered approaches to clinical research.

"With the REMOTE virtual trial pilot, for the first time we can make it possible for patients to participate in clinical trials without having to visit physical sites," said Pfizer Executive Vice President and Chief Medical Officer Freda Lewis-Hall, M.D., who announced the new trial today during remarks at the National Library of Medicine (NLM) Clinical Trials Conference in Bethesda, MD. "Studies like REMOTE could make biomedical science much more accessible to people who have long been excluded from or under-represented in clinical trials. Putting research within reach of more diverse populations has the potential to advance medical progress and lead to better outcomes for more patients."

The REMOTE trial is the first-ever randomized "virtual" clinical trial under an IND application to secure patient consent online using video/multimedia and online testing. Study investigators will ship all blinded study medication to patients at home rather than dispensing it at a clinic visit. Researchers will manage study conduct remotely, and share clinical trial data and results with patients, enabling them to add them to their own personal health records.

Clinical Trials 101

Before they can be approved and marketed, experimental therapies must complete the clinical trial journey, during which it is determined if a therapy is safe and effective. Clinical trials are conducted in phases during which key questions are addressed. The clinical trial process usually entails considerable hurdles. Clinical trials take an average of eight years to complete, cost thousands of dollars for each participant, and often struggle to recruit enough participants. The majority of studies will not reach their ultimate destination. But those that do represent true advances in medicine.

Pre-trial

The process begins with an idea that translates into some form of therapy, often tested first at the cellular level. It might then proceed to be tested on animals. If the therapy appears safe and effective in these pre-clinical studies, it will be tested on humans in a clinical trial.

≈ 4½ years

The Research Protocol

The principal investigator (PI) is the researcher leading the clinical trial. The PI and/or sponsor (e.g., a pharmaceutical company) create a detailed plan—the research protocol—spelling out the study's scientific design, who can and can't enter the study, procedures, the potential risks, how participants will be followed and monitored to assess side effects, how endpoints will be measured, and how the data will be evaluated to determine the benefits of the research. As with all clinical trials, approval by an Institutional Review Board (IRB*)—an independent ethics committee—is required for the research protocol. In many cases, the research protocol must also be approved by the Food and Drug Administration (FDA).

≈ ½ year

When

A protocol is written for each study, at every stage of development.

Translational Trials

Translation is the process of getting a new therapeutic idea from the laboratory into the clinic. These clinical trials are often the first time that a new therapy is administered to humans. Many seemingly promising ideas don't pass this stage because of imperfections. Translational trials are typically small and use biological measures rather than clinical outcomes to decide the likely worth of a new therapy and what studies should be done next. A frequent outcome of a translational clinical trial is that more laboratory experiments must be done prior to additional human studies.

≈ 1 year

Why

To translate basic research findings more quickly and efficiently into new approaches for prevention, diagnosis, and treatment of disease.

Dose-Finding (Phase I)

These early developmental trials are often intended to find the optimal dose of the new therapy or technique and the best way to administer it. Researchers want to see how the body reacts to the treatment, and whether it causes any side effects. Blood samples as well as clinical side effects are typically used to help determine the best dose.

≈ ½ year

Who

Generally, two to three dozen people participate in a dose-finding clinical trial. For some therapies, Phase I participants have been healthy volunteers who are not being treated for any disease. However for many life-threatening diseases, such as cancer, Phase I participants are individuals who have not responded well to standard treatments and are seeking better therapeutic options.

Safe
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upward

Wh
Phase II
conduct
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* Cedars-Sinai's Institutional Review Board (IRB) is the entity responsible for overseeing all research activities involving human subjects conducted at Cedars-Sinai. Cedars-Sinai's IRB operates under a Federalwide Assurance (FWA) approved by the Department of Health and Human Services that requires the hospital to conduct all federally supported human-subjects research in accordance with federal regulations and the Belmont Report's ethical principles of respect for persons, beneficence, and justice. The Cedars-Sinai Human Subjects Protections Program is fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

Key:

- Positive Outcome
- Review by Independent Panel of Experts
- Neutral or Negative Outcome: Trial Ends Here
- Protocol Development Data Analysis and Publication

Proteus, Oracle launch integrated software, ingestible sensors for clinical trials

By: Jonah Comstock | Jan 12, 2015 Tweet 144 Share 402 Share 37

Tags: ingestible pill | Oracle | Oracle clinical trials | Oracle Corporation | Oracle Health Sciences InForm Medication Adherence Insights Cloud Service | Oracle InForm | pill sensor | Proteus Digital Health | Proteus Digital Health feedback system |

Ingestible sensor company Proteus Digital Health and computer giant Oracle have integrated Proteus's digital health feedback system, which includes an ingestible pill sensor, a wearable patch, and a software system, with Oracle's InForm software for data collection. Clinical trial researchers using Oracle's software will now be able to track patients' medication adherence with Proteus's technology.

"Oracle Health Sciences InForm Medication Adherence Insights Cloud Service helps health sciences organizations effectively address two long-standing and complex challenges: measuring participant adherence to drug protocols and identifying the optimum dosing regimen for recommended use," Steve Rosenberg, senior vice president and general manager of Oracle Health Sciences, said in a statement. "This groundbreaking solution — the direct result of a collaboration between Oracle and Proteus Digital Health — is a powerful example of how we can rapidly combine our industry-leading clinical trial data capture and management solutions with emerging technologies, such as digital pills, to help health sciences organizations transform the drug development and approval process."

Oracle and Proteus's partnership has been on the horizon since May 2013, when **Oracle led a $45 million funding raise for Proteus** and announced that the two would work together to help investigators in clinical trials to better understand and measure medication ingestion, dose timing, and associated physiologic responses from patients.

Clinical trial researchers using Oracle's software will now be able to track patients' medication adherence with Proteus's technology.

- Measuring participant adherence to drug protocols
- Identifying the optimum dosing regimen for recommended use

Jan 12, 2015

Leaf Healthcare

Each year, over 1 million patients
will suffer from a hospital-acquired pressure ulcer.

The total cost of treating pressure ulcers
in the United States per year is ~$10B.

Patient Identification

Room Number and Patient Initials are clearly displayed for easy patient identification and tracking.

Turn Status Indicator

A simple color bar is recognizable at a glance. Green is all-good, Yellow means an action is coming up, and Red indicates an action is overdue.

Qualifying Information

Upright (in bed or in a chair) and Prone positional qualifiers are displayed when warranted. System status and notices display as well.

Room	Patient	Time Until Next Turn	Position	Information
2301	M.S.	1:57	L **B** R	Upright
2302	C.M.	0:14	**L** B R	
2303	S.S.	Turn Due 0:03 Over	L B **R**	
2304	M.L.	1:51	~~L~~ B R	Prone

Turn Priority

The digital timer counts down to a turn being due, and then begins to count up after a turn due alert to help prioritize and coordinate necessary actions within workflow.

Patient Position

Accurately displays the real-time position of each patient. If desired, any patient specific position can be set to alert in order to avoid pressure to a known high risk area.

California hospital's patient safety protocols now require a wearable

By: Jonah Comstock | Dec 3, 2014

Tags: Chino Valley Medical Center | El Camino Hospital | FDA 510(k) clearance | Leaf Healthcare | Leaf Patient Monitoring System | pressure ulcers | VA | Veterans Affairs |

A California hospital has begun requiring certain patients use a wearable remote patient monitoring device in order to comply with internal patient safety protocols. Chino Valley Medical Center is employing the Leaf Patient Monitoring System from Pleasanton-based Leaf Healthcare.

The sensor monitors patient movement in bed, then uses that data to calculate when the patient needs to be turned to prevent the formation of pressure ulcers. That data is uploaded wirelessly to central monitoring stations or mobile devices so clinicians can monitor the readings. The system also alerts nurses or staff when a patient needs to be turned.

A recent clinical trial showed that use of the sensor increased compliance with hospital turn procedures from a baseline 64 percent to 98 percent. Ulcers are a dangerous and painful condition which cost the US healthcare system $11 billion a year according to AHRQ, and because they're hospital-acquired, treatment is often not reimbursable by insurers.

Chino Valley Medical Center will require that any patient who scores 18 or lower on the Braden Scale for Predicting Pressure Ulcer Risk use the sensor.

"Our experience with the Leaf Patient Monitoring System showed that it offers a breakthrough in patient care and safety," Dr. James Lally, chief medical officer of Chino Valley, said in a statement. "The vigilance of our staff in regards to prevention methods has enabled Chino Valley to substantially reduce the incidence of reportable pressure ulcers at our facility. The Leaf Patient Monitor will help

Using the device increased compliance with hospital turn protocols – a standard of care to prevent pressure ulcers – from a baseline of 64 percent at the start of the trial to 98 percent after the monitoring system was deployed.

Dec 3 2014

Pharmaceuticals

Biogen Straps Fitbits Onto MS Patients' Wrists

By Caroline Chen | December 23, 2014

Amateur athletes use fitness bands like the Fitbit to track their adrenaline-fueled adventures and then brag to friends. Others use the band to count their footsteps and the calories they burn. Drugmaker Biogen Idec (BIIB) is exploring ways to use fitness trackers to gather data from people who suffer from multiple sclerosis, an autoimmune disease that affects the brain and spinal cord.

The company, which has five MS drugs on the market, gave out 250 Fitbit bands to MS patients in the U.S. last spring to track their level of activity and sleep patterns. Mobility is affected by the disease, and Biogen says collecting data on a daily basis —about how much and how fast MS patients walk, for example—could yield data about the progression of the disease and lead to better treatments.

"Let's say you see a patient four times a year—that's two hours per year," says Al Sandrock, Biogen's chief medical officer. "You're losing 364.9 days of other data that could be collected."

STORY: Fitbit for Testosterone Junkies: Health-Tracking Gadgets Reach the Molecular Level

The data also could help Biogen prove the value of its pricey medications to health insurers and pharmacy benefit managers, who are responding to rising drug prices by reducing the number of medicines covered. "It's a smart investment," says Tim Coetzee, chief research officer of the National MS Society. Express Scripts (ESRX) dropped Bayer's (BAYN:GR) MS drug Betaseron, directing patients to three other options, including Biogen's Avonex. MS drugs cost at least $50,000 a year at wholesale prices, Coetzee says. "Having the tools to demonstrate the value of a particular agent is valuable," he says.

"Betaseron is comparably priced to other MS treatments," says Rosemarie Yancosek, a Bayer spokeswoman.

Decisions about which drugs to cover

- Biogen Idec, 다발성 경화증 환자의 모니터링에 Fitbit을 사용
- 고가의 약 효과성을 검증하여 보험 약가 유지 목적
- 정교한 측정으로 MS 전조 증상의 조기 발견 가능?

Dec 23, 2014

Anatomy of a Nymi

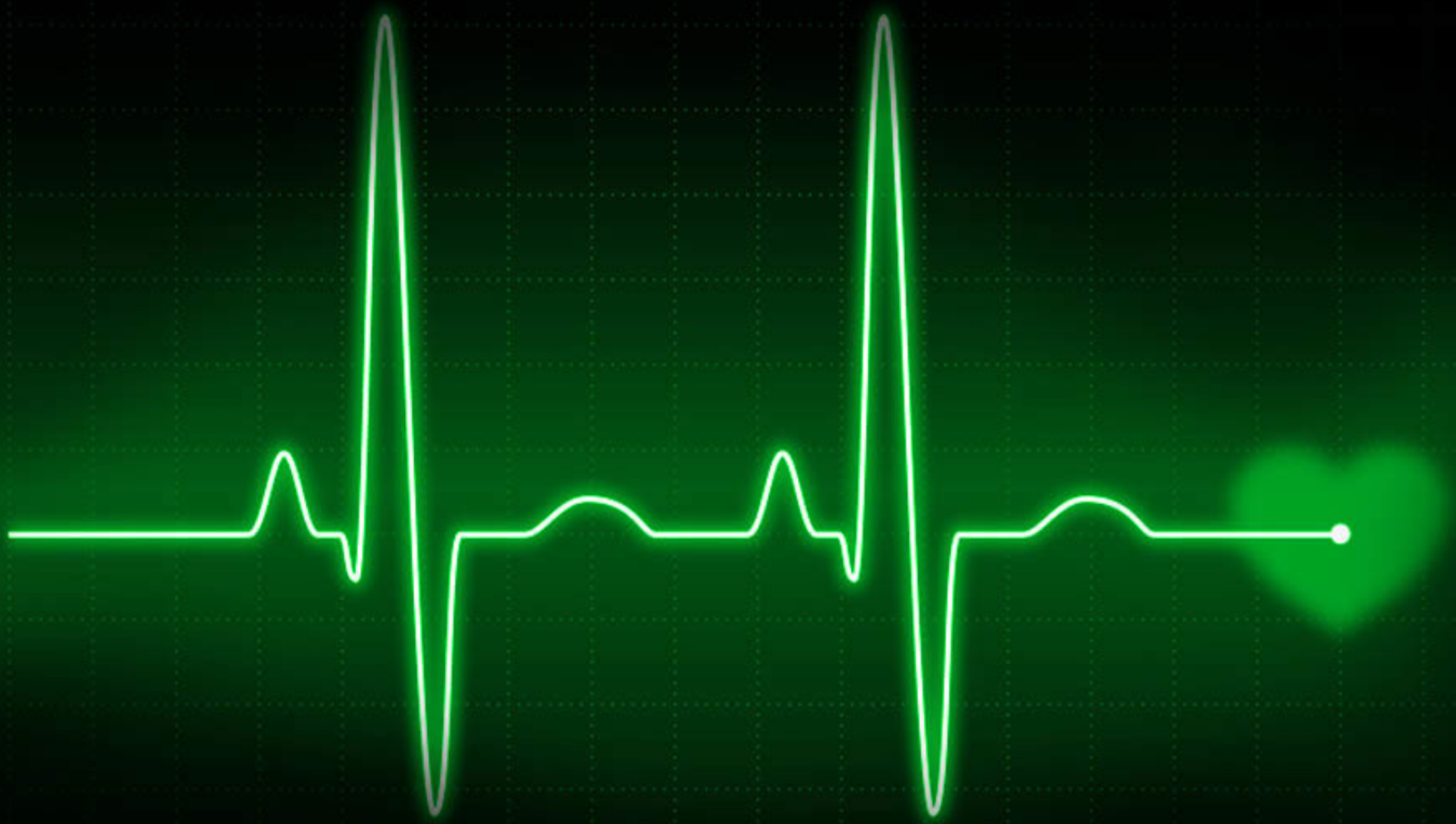
EARTID

CONNECTIVI

ON SENSING

PERSONAL DE

PROXIMITY DETECTION



SECURE AUTHENTICATION

USING YOUR CARDIAC RHYTHM

Steve

The Telegraph

Home Video News World Sport Finance Comment Culture Travel Life Women Fa

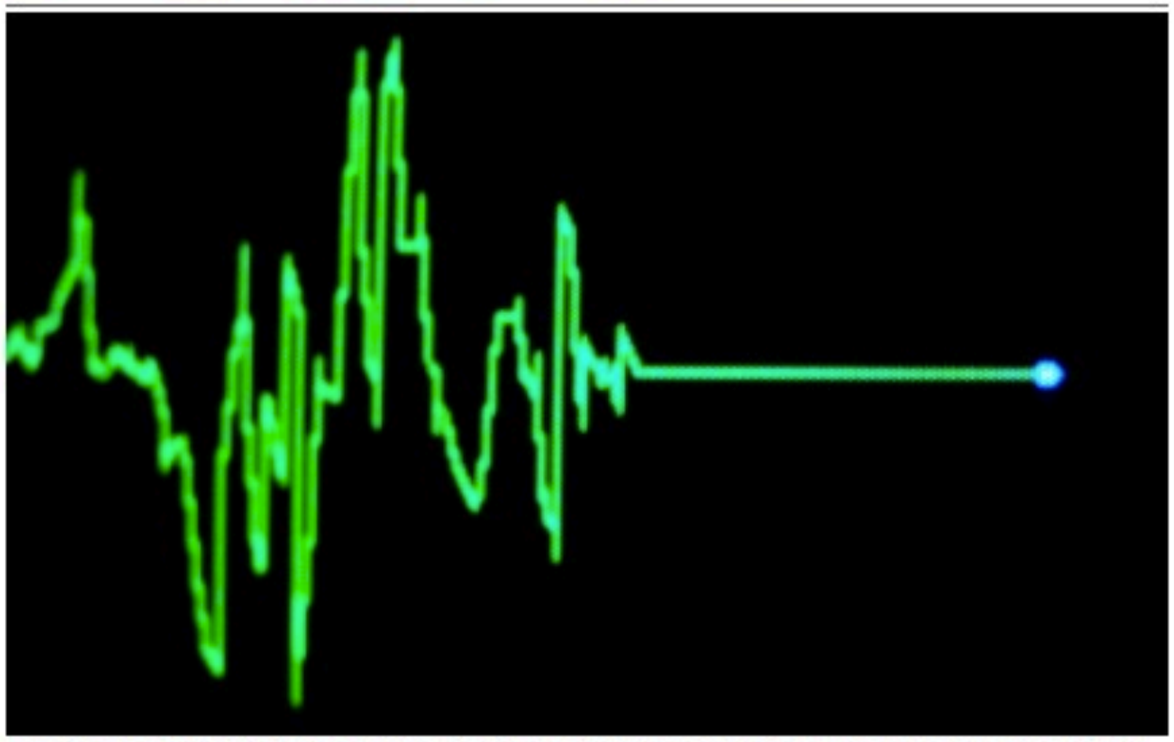
Budget | Companies | Comment | Personal Finance | ISAs | Economy | Markets | Property | Enter

ISAs | Investing | Pensions | Savings | Interest Rates | Funds | Mortgages | Credit Cards | Expat Mor

HOME » FINANCE » PERSONAL FINANCE » BANK ACCOUNTS

Forget your bank PIN: Halifax trials technology where customers are recognised by their heartbeat

Halifax is testing new biometric technology where customers will prove their ID through the unique rhythms of their heartbeats



Heartbeat analysis could become widespread in banking and other industries where secure methods of ID are required Photo: DESIGN PICS INC./ALAMY

By Richard Dyson
8:55AM GMT 13 Mar 2015

3 Comments

Halifax is believed to be the first British bank to trial technology which will allow customers to prove their identity through the analysis of their heartbeat.

Strings of passwords, login codes, PIN numbers and memorable words that we

- 영국의 은행 Halifax 가 Nimbi 밴드를 개인 인증에 사용 고려
- 웨어러블 기기를 통한 데이터 수집 시에도 활용도 높을 것

March 13, 2015

3D Printer

3D 프린터로 구현하는 맞춤 의료

STAR TREK
INTO DARKNESS
3D

IN IMAX, DIGITAL 3D AND 2D CINEMAS

PARAMOUNT PICTURES AND SKYDANCE PRODUCTIONS PRESENT A BAD ROBOT PRODUCTION A J.J. ABRAMS FILM "STAR TREK INTO DARKNESS" JOHN CHO BENEDICT CUMBERBATCH ALICE EVE BRUCE GREENWOOD SIMON PEGG CHRIS PINE ZACHARY QUINTO ZOË SALDANA KARL URBAN PETER WELLER ANTON YELCHIN VISUAL EFFECTS AND ANIMATION BY INDUSTRIAL LIGHT & MAGIC

MUSIC BY MICHAEL GIACCHINO COSTUME DESIGNER MICHAEL KAPLAN EDITED BY MARYANN BRANDON, A.C.E. MARY JO MARKEY, A.C.E. PRODUCTION DESIGNER SCOTT CHAMBLISS DIRECTOR OF PHOTOGRAPHY DAN MINDEL, A.S.C., B.S.C. EXECUTIVE PRODUCERS JEFFREY CHERNOV DAVID ELLISON DANA GOLDBERG PAUL SCHWAKE PRODUCED BY J.J. ABRAMS BRYAN BURK DAMON LINDELOF ALEX KURTZMAN ROBERTO ORCI BASED UPON "STAR TREK" CREATED BY GENE RODDENBERRY

SKYDANCE PRODUCTIONS

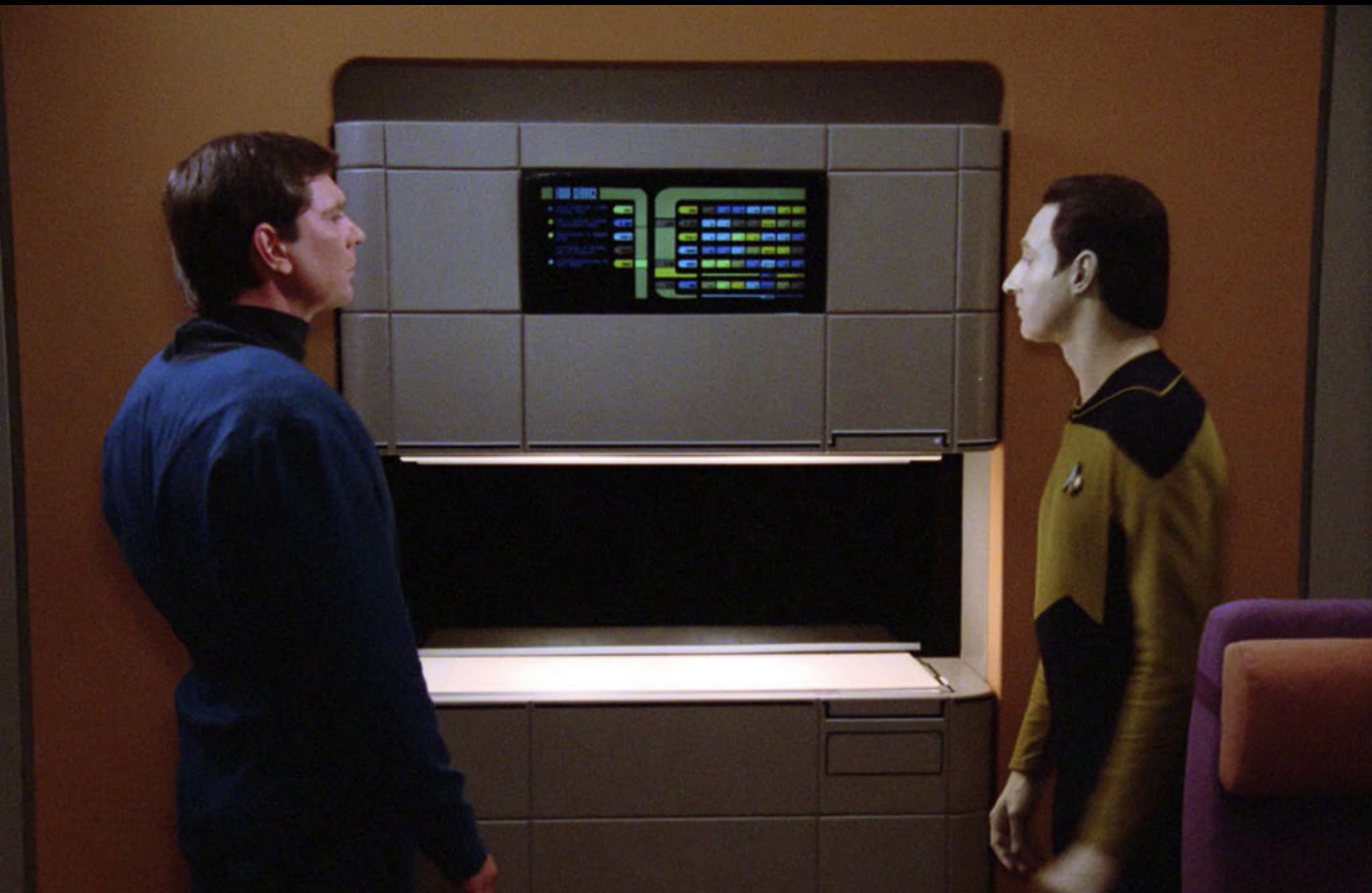
WRITTEN BY ROBERTO ORCI & ALEX KURTZMAN & DAMON LINDELOF

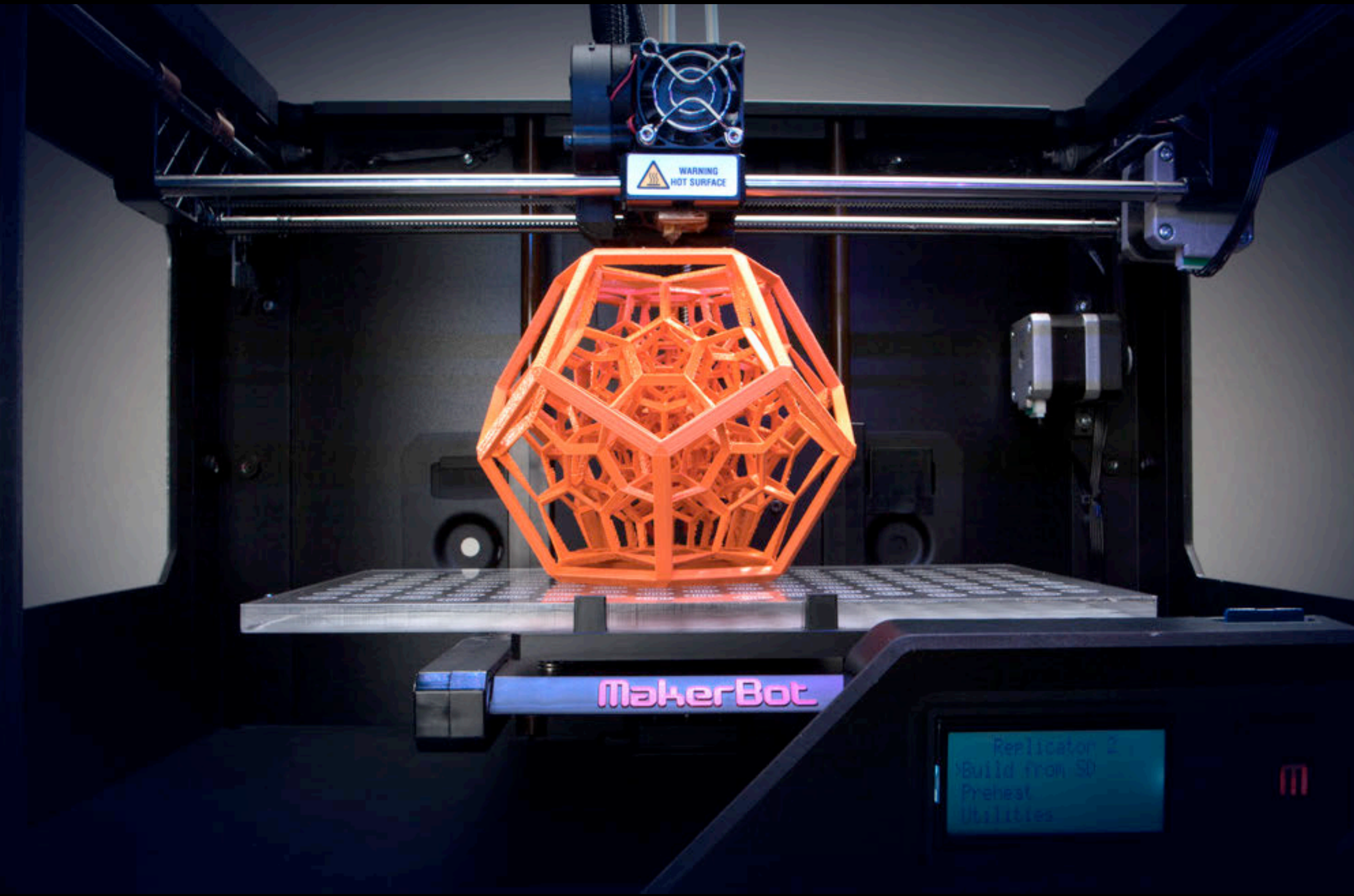
IN CINEMAS MAY 9

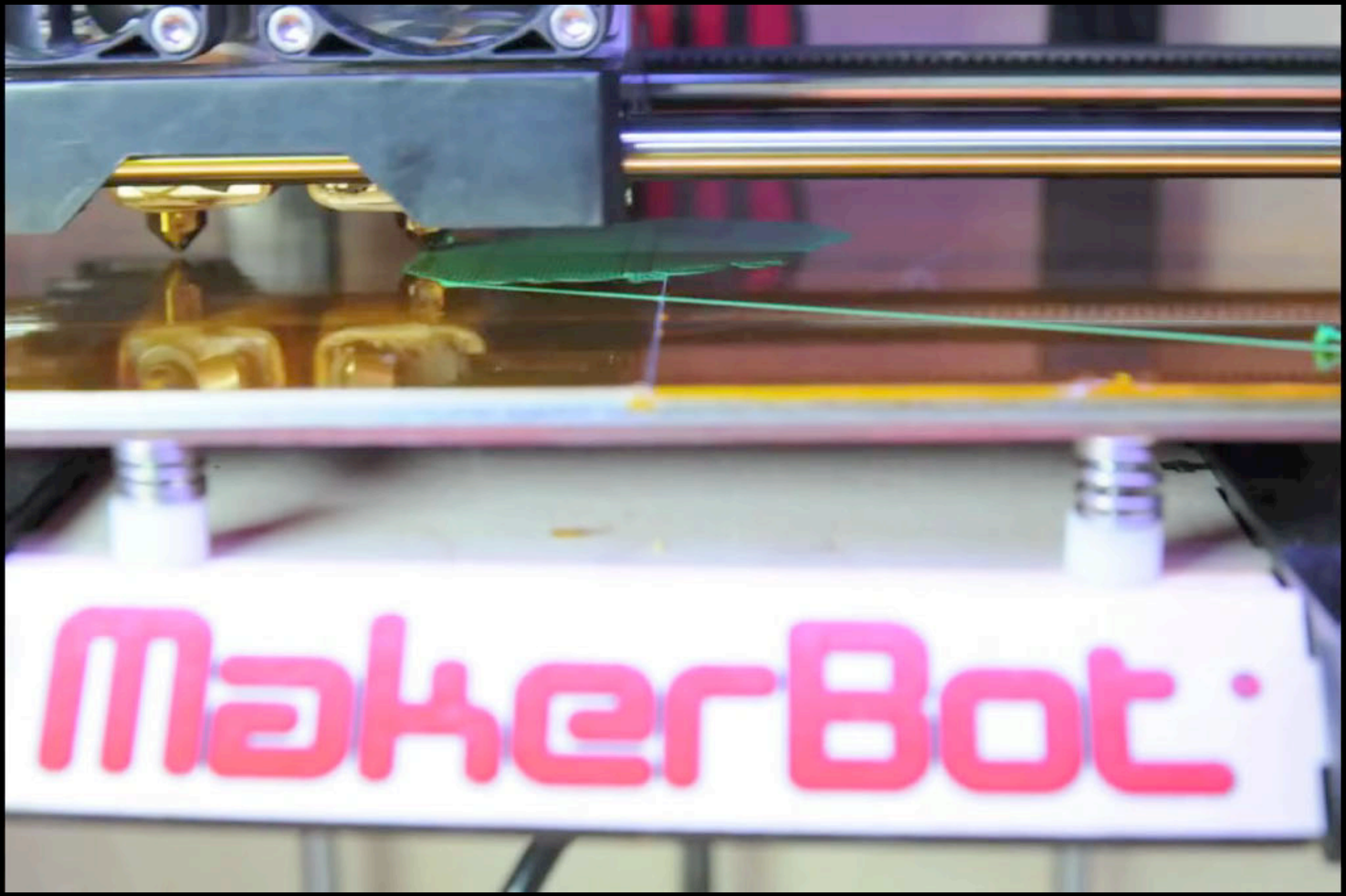
DIRECTED BY J.J. ABRAMS

StarTrekTheMovie.co.uk

Replicator

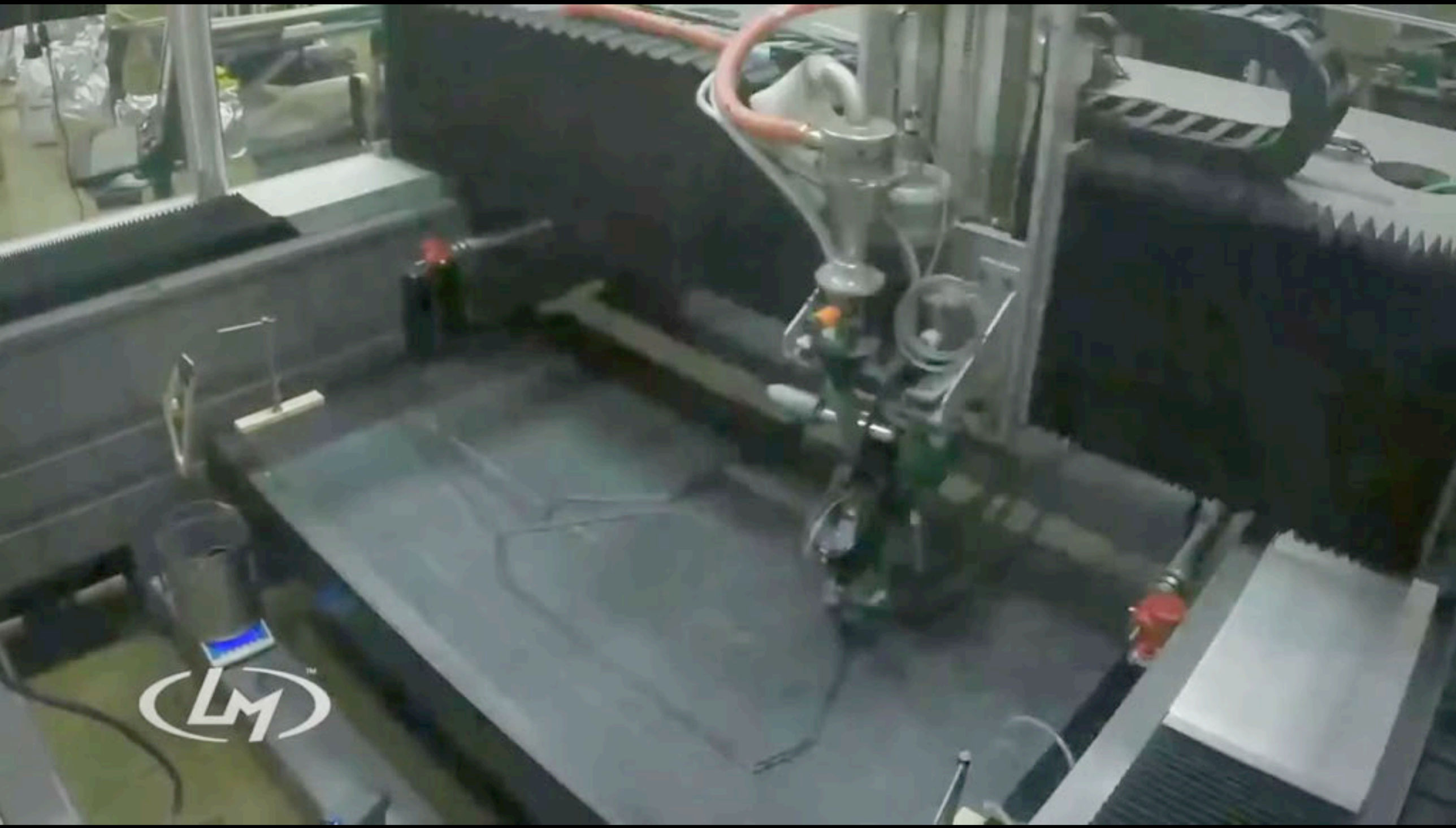



WARNING
HOT SURFACE
MakerBot
Replicator 2
>Build from SD
Preheat
Utilities


MakerBot

Winsun: 3D Printed House

Winsun: 3D Printed House




IMTS
2014

3D Printed Hearing Aid

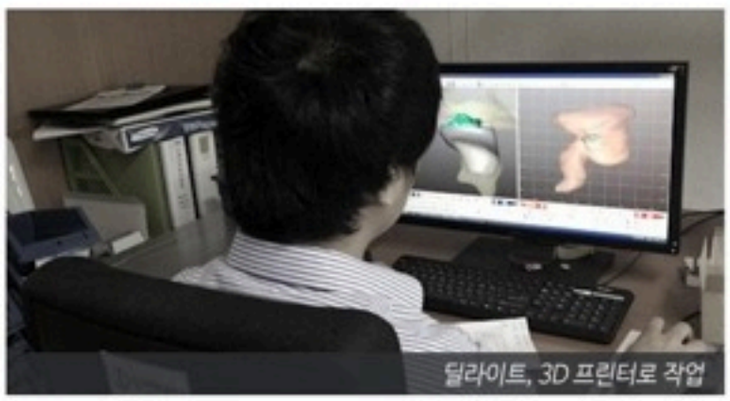
딜라이트보청기
Delight Hearing Aid

이온 2채널 34만원
환급금 최대 34만원

딜라이트 소개 | 제품 안내 | 방문 예약 | 고객 문의 | 평생 안심 AS 센터 | 국가보조금 안내 | 이달의 이벤트

이 제품은 의료기기이며, '사용상의 주의사항'과 '사용방법'을 잘 읽고 사용하십시오.
광고심의필 : 심의번호 2014110121145

합리적인 가격 믿을 수 있는 제품!
딜라이트 보청기입니다.


딜라이트, 3D 프린터로 작업

딜라이트, 3D 프린터로 귀에 꼭 맞는 보청기 제작

2011년부터 3D 스캐너와 3D프린터 기술을 도입하여 사람의 손으로 구현하기 힘든 정밀한 작업까지도 가능합니다. 뿐만 아니라 3D 장비를 통한 대량생산은 제품의 가격경쟁력을 만들며 귀 모양의 스캔 데이터는 CRM 자료로 보관되어 분실 시 언제든 재제작이 가능하다는 장점이 있습니다.

고객님의 귀에 더 잘 맞는 제품으로
보청기 착용에 대한 만족도를 높일 수 있도록 노력하겠습니다.

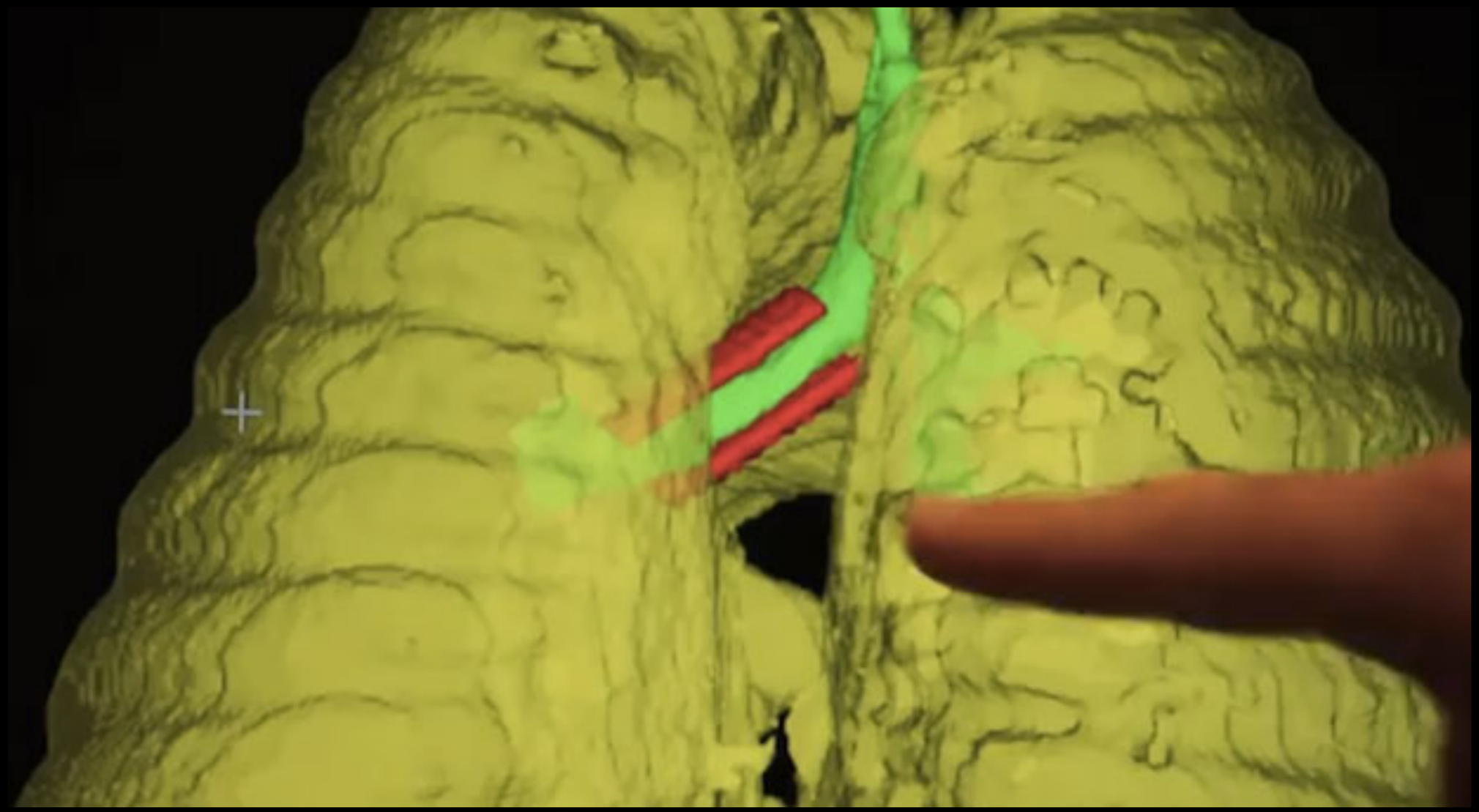
3D Printed Teeth

3D Printed Jaw

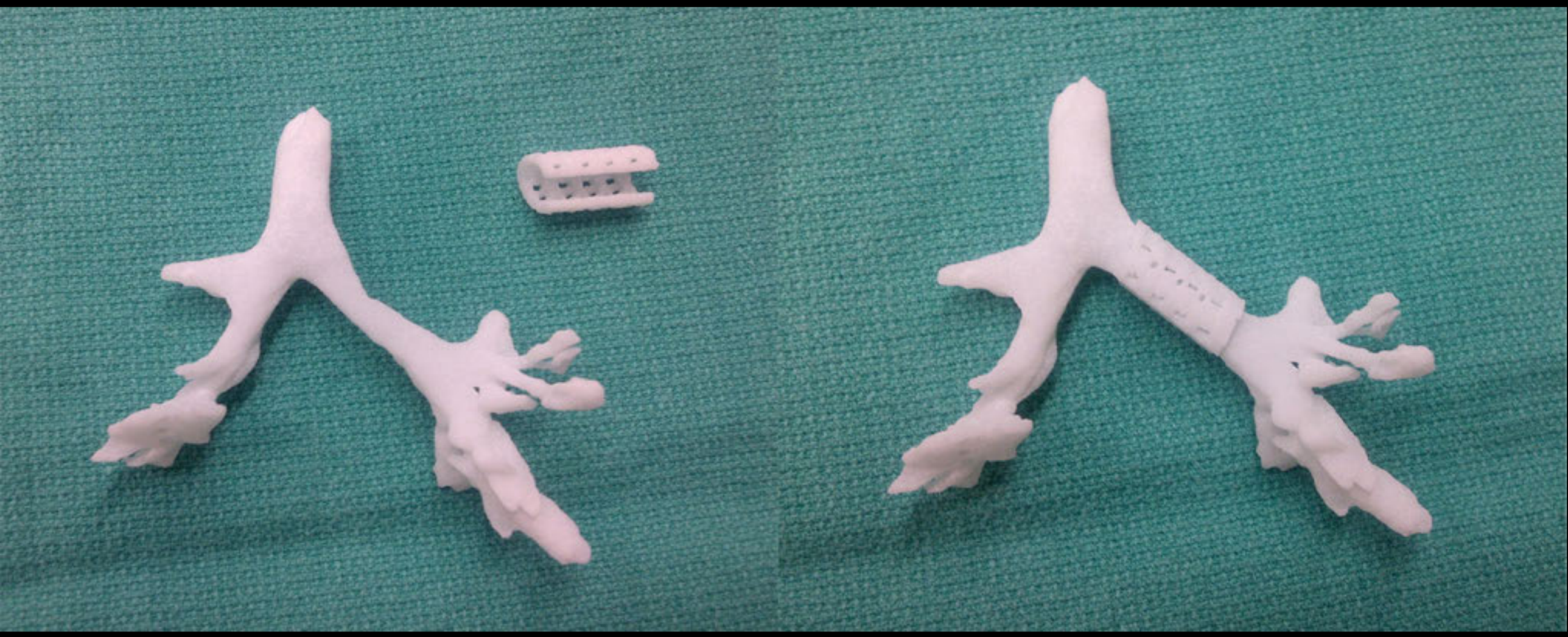
3D Printed Jaw

기관기관지연화증 (tracheobronchomalacia)

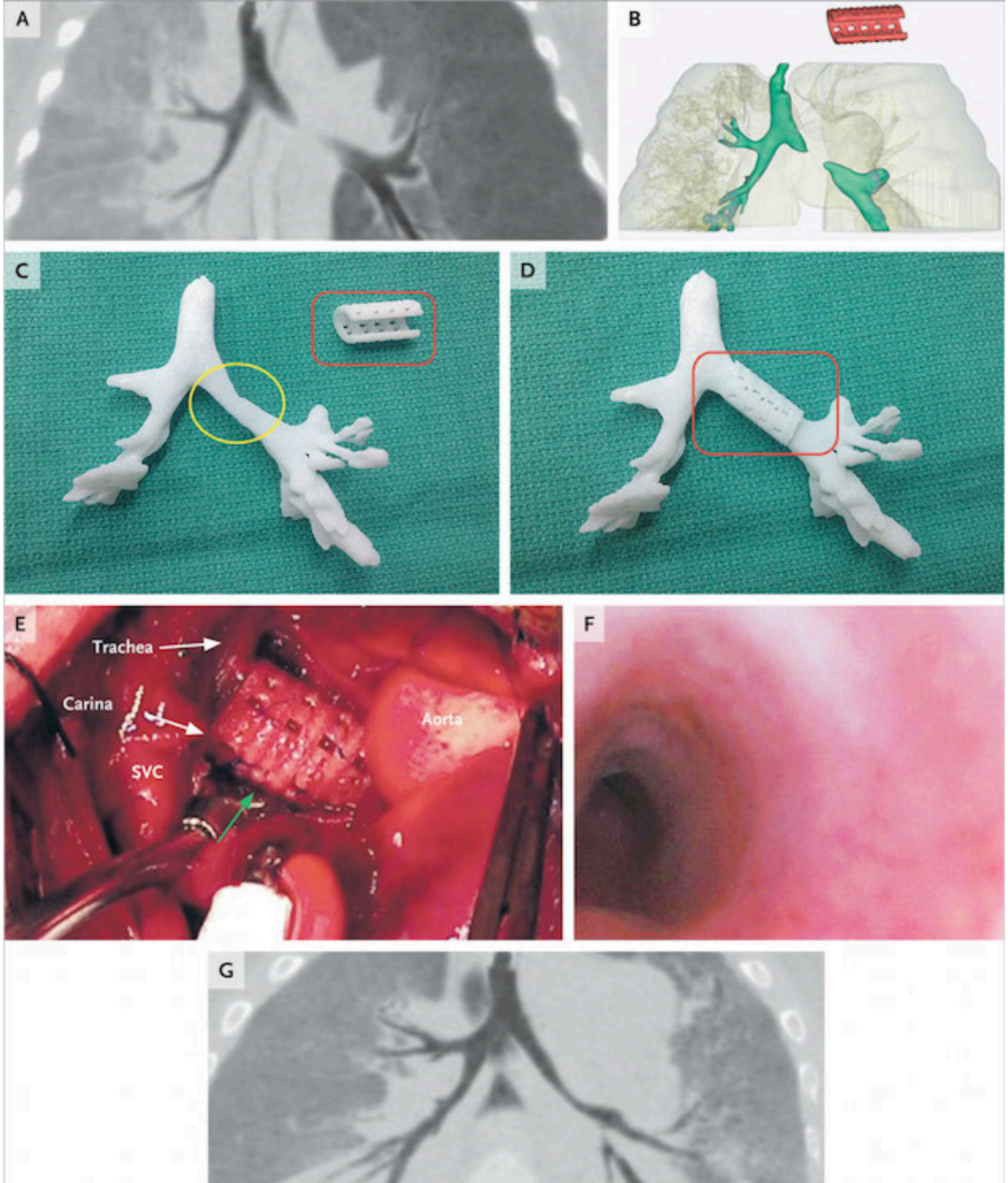
3D Printing Is a Matter of Life and Death



3D Printing Is a Matter of Life and Death



N Engl J Med 2013; 368:2043-2045



N Engl J Med 2013; 368:2043-2045

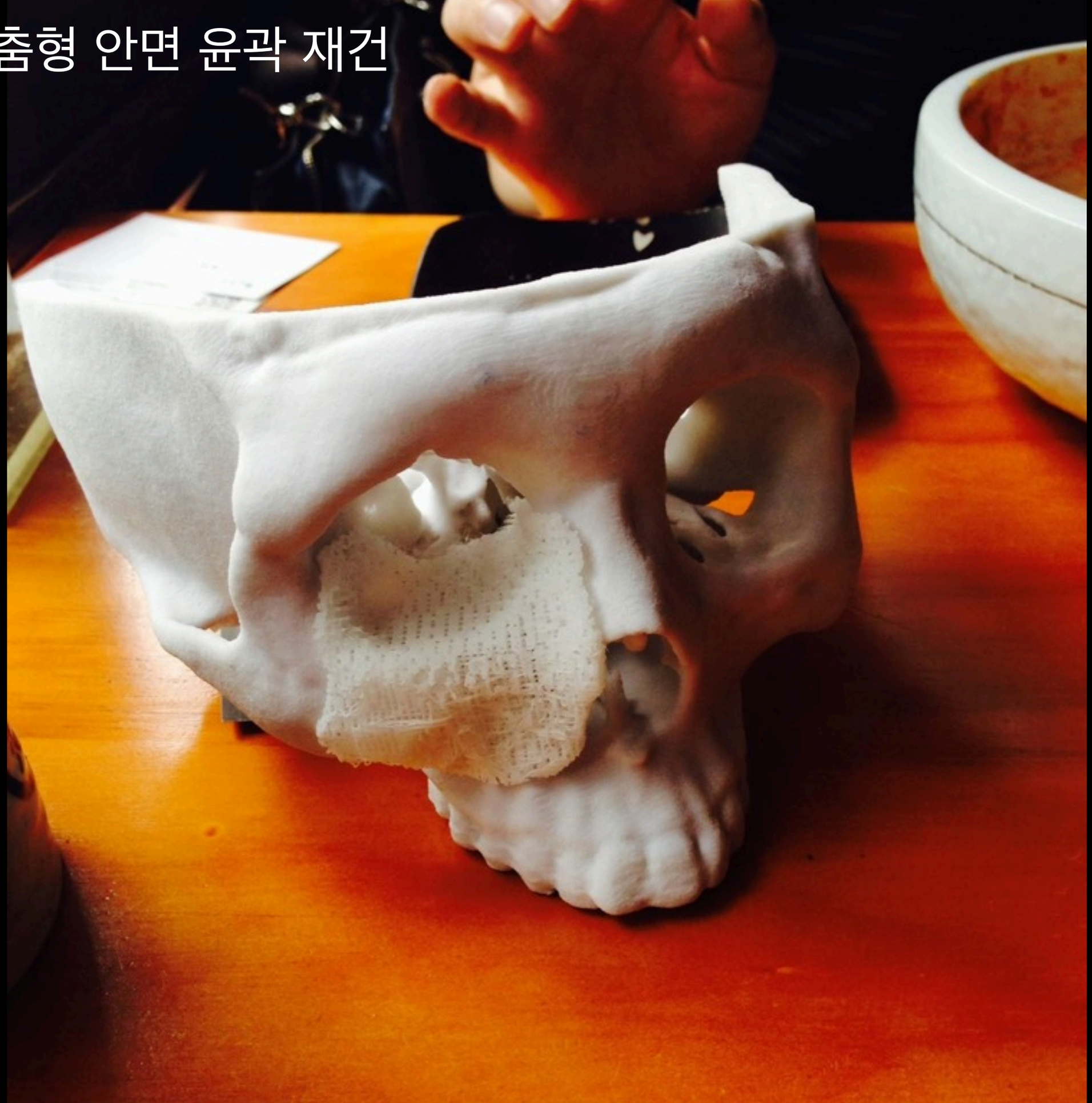
3D Printed Skull

22세 네델란드 여성 환자
2014.3

3D Printed Skull

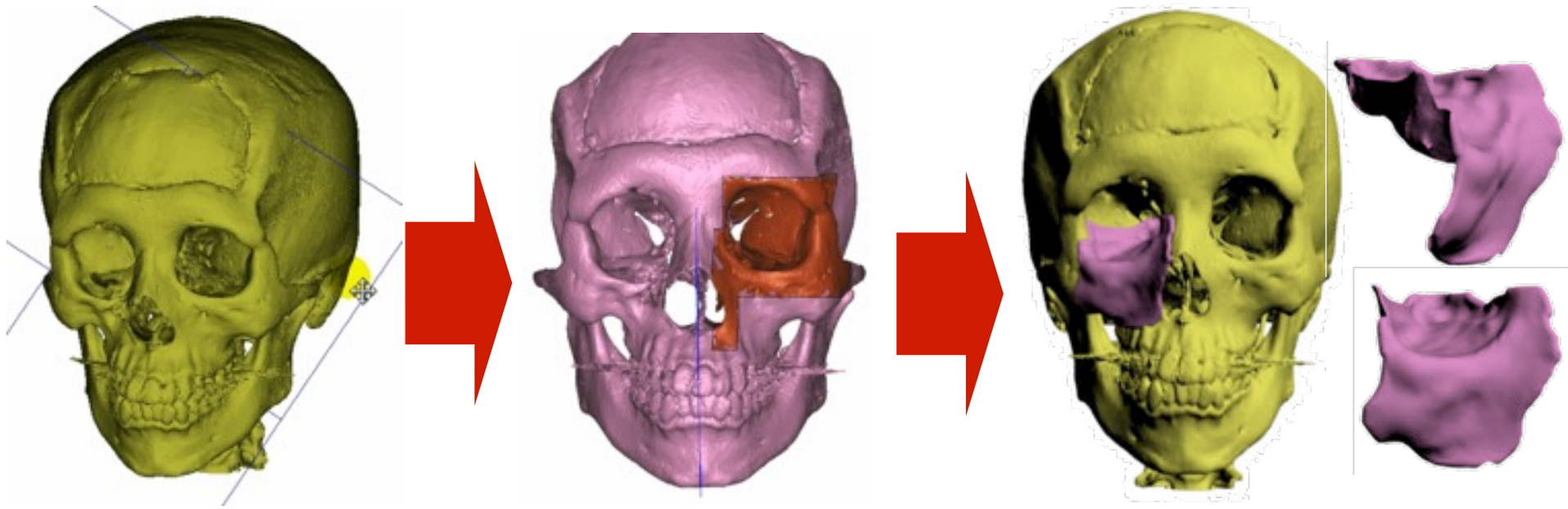
환자 맞춤형 안면 윤곽 재건

환자 맞춤형 안면 윤곽 재건



The Korean first KFDA approved 3D-printed biodegradable scaffold (09. 2014)

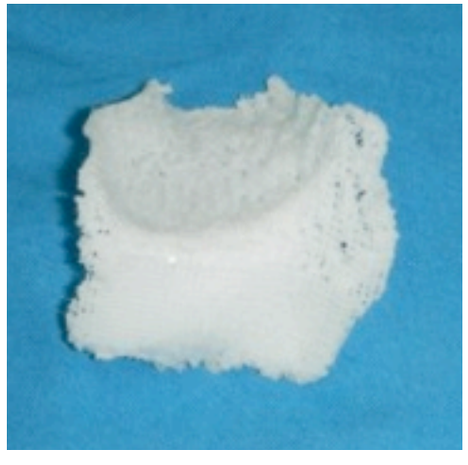
- Min-Hyeong Heo, 18 years old
- Acquired deformity by cancer (myxoid chondrosarcoma) therapy at age 10
- Asymmetric eyes' height; Depressed malar region



Patient's skull model exported from CT image

Mirrored normal region model (left side) into depressed region (right side)

Implantation into skull



3D printed polycaprolactone (PCL) scaffold

* Co-work group : Dr. Jong Won-Rhie, Department of Plastic and Reconstructive Surgery, The Catholic University of Korea (Seoul St. Mary's Hospital)
/Dr. Dong-Woo Cho, Department of Mechanical Engineering, POSTECH/ T&R Biofab (Bio venture company in Korea)

Implantation of 3D printed biodegradable scaffold (degradation period 2~3 years)

Pre-op | post-op (4d) | post-op (2wk) | post-op (4wk)

* Co-work group : Dr. Jong Won-Rhie, Department of Plastic and Reconstructive Surgery, The Catholic University of Korea (Seoul St. Mary's Hospital)
/Dr. Dong-Woo Cho, Department of Mechanical Engineering, POSTECH / T&R Biofab (Bio venture company in Korea)

2014.10.02

with the courtesy of prof. Jin-Hyung Shim (Korea Polytechnic University)

Smart/Mobile Healthcare

스마트/모바일 헬스케어

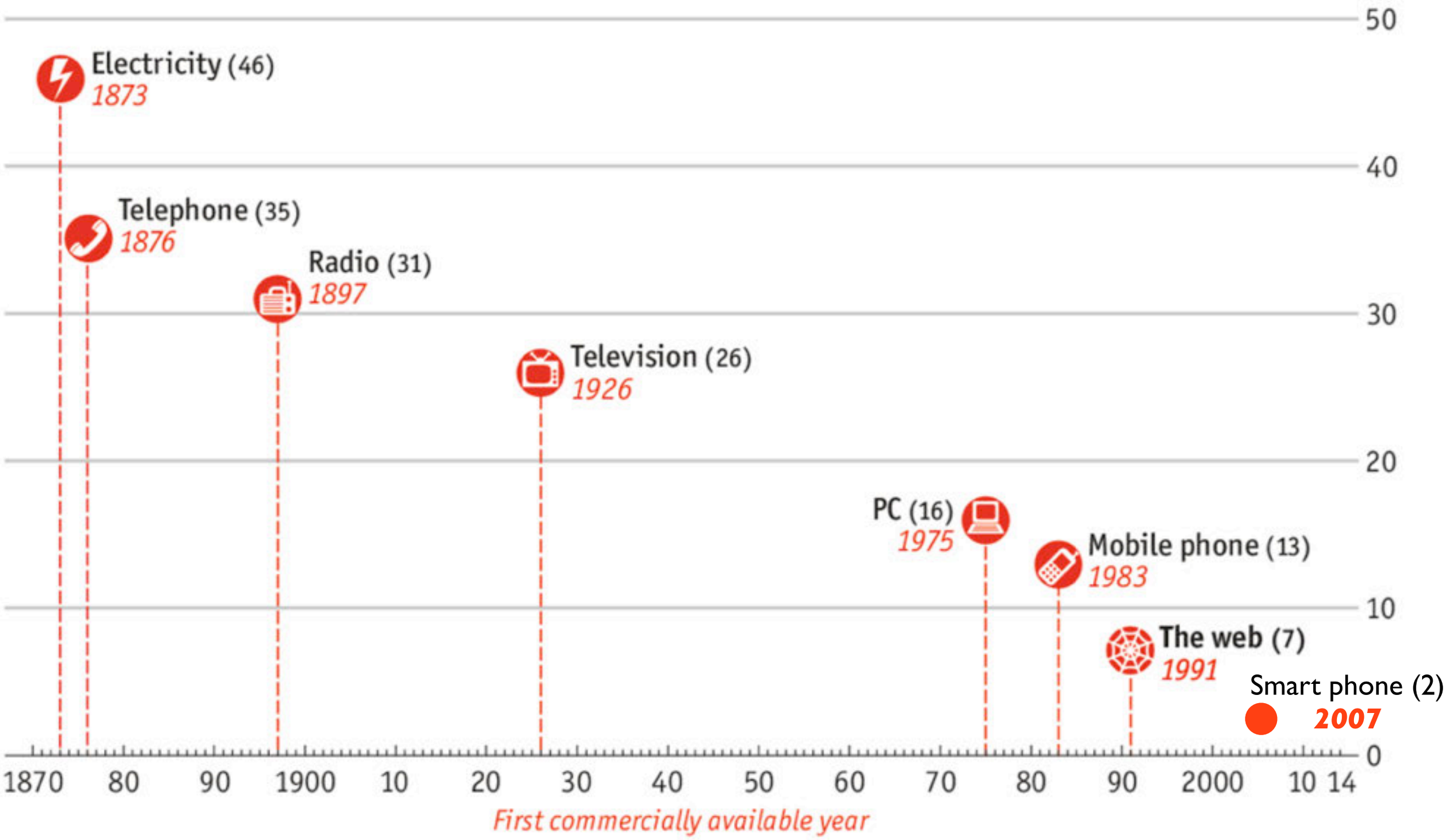
2013년에는 어떻게 바뀌었을까요?


2005
Luca Bruno / AP


2013
NBC NEWS
Michael Sohn / AP

Technology adoption

Years until used by one-quarter of American population



Source: Singularity.com


VIA 9GAG.COM
SPORTS

CellScope's iPhone-enabled otoscope

PEEK (portable eye examination kit)

http://www.peekvision.org

Kinsa Smart Thermometer

Withings Wireless Blood Pressure Monitor

iPhone Breathalyzer


AT&T 3G
1424
Annuler
Enregistrer

AliveCor Heart Monitor


AliveCor

Dr. Eric Topol on AliveECG

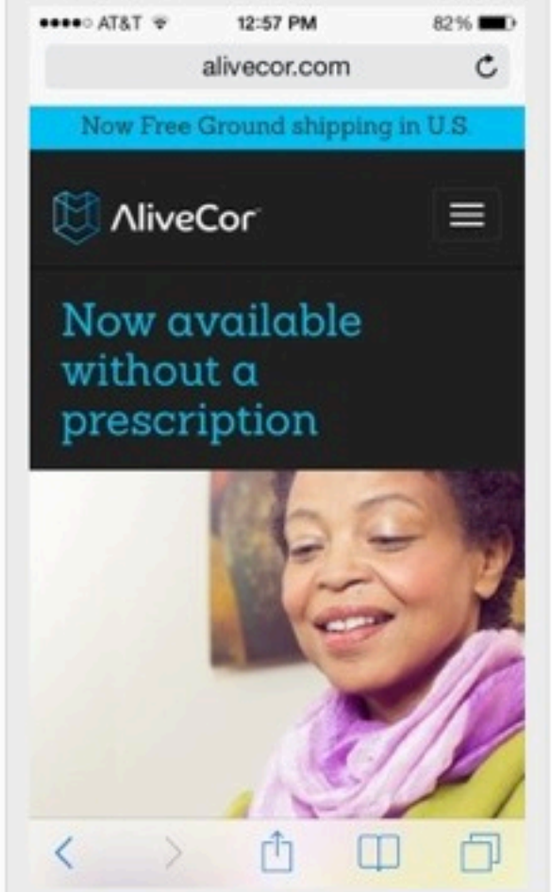
- Eric Topol, MD, Ph.D.
  - 스크립스 중개과학 연구소 소장
  - 세계적 심혈관계질환 전문의 (Vioxx 퇴출 주도)
  - 디지털 헬스케어 전도사, '청진기가 사라진다'의 저자

Heart Monitor of AliveCor

- 2012년 12월 FDA 승인
  - 처음에는 전문의들에게만 판매
  - 이후, 의사의 처방이 있으면 환자들도 구입 가능
- 환자들이 평소에 자신의 심장 부정맥을 관찰할 때 사용 가능
  - 부정맥이 발생하는 순간 심전도를 스스로 측정, 기록, 전송 가능

AliveCor ECG is approved for over the counter sales

7 hours ago *by* Satish Misra, MD



AliveCor today announced that its smartphone compatible ECG monitor has been approved by the FDA for over the counter use.

For those not familiar with the AliveCor device, this smartphone peripheral enables users to capture single lead ECG tracings on demand similar to some traditional event recorders. The elegant and simple design of the AliveCor Heart Monitor, however, separates it from most of the currently available devices.

iMedicalApps did an in-depth review of the AliveCor Heart Monitor in which we looked at not only the device itself but the potential real-world applications. Overall, we were quite impressed with the design of the device and its associated app. We did however feel that many applications being advertised for device, such as routine atrial fibrillation screening, were of questionable validity in terms of providing meaningful benefits on a population level. However, there are some more targeted situations where the device has real potential benefits like monitoring for paroxysmal symptomatic arrhythmia. In addition, there are highly health literate patients for whom such data helps them feel more in control of their health.

Overall, the availability of this device over the counter is in all likelihood a double edged sword. Innovative users may, for example, help discover or develop novel applications for this technology that have meaningful benefits. For others, the availability of the device over the counter may drive over-testing or increased healthcare utilization driven by device artifact or benign findings (think "nonspecific ST-T wave change").

At the end of the day, a combination of individual experimentation and systematic evaluation will be needed to guide how devices like the AliveCor Heart Monitor can be used in the right situation with the right patient to improve outcomes.

2014년 2월 10일

Over the counter 판매 FDA 승인

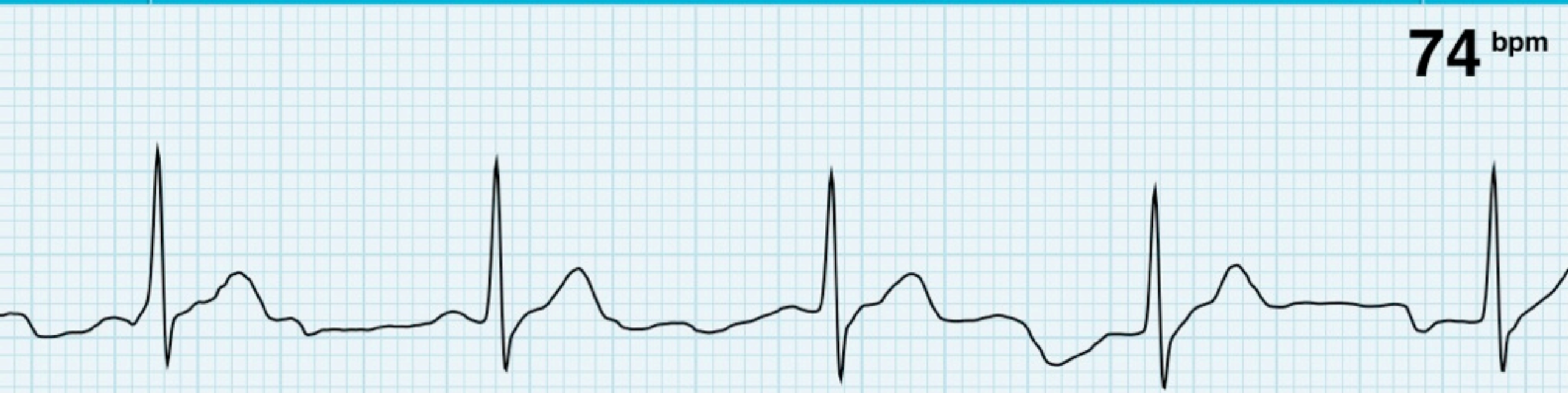
의사의 처방 없이,
일반인들도 구매 가능

●●●●● olleh LTE 오전 8:31 98%

Yoon Sup Choi 1982. 12. 11.

2014. 4. 1. 오전 8:28:47

74 bpm



ECG ANALYSIS

Enhanced Filter

●●●●● olleh LTE 오전 8:29 99%

Add Notes

MY SYMPTOMS

- [x] No symptoms
- [ ] Palpitations 심계항진
- [ ] Dizziness 어지럼증
- [ ] Shortness of breath 호흡곤란
- [ ] Fatigue 피로감
- [ ] Chest pain 가슴 통증

MY ACTIVITIES

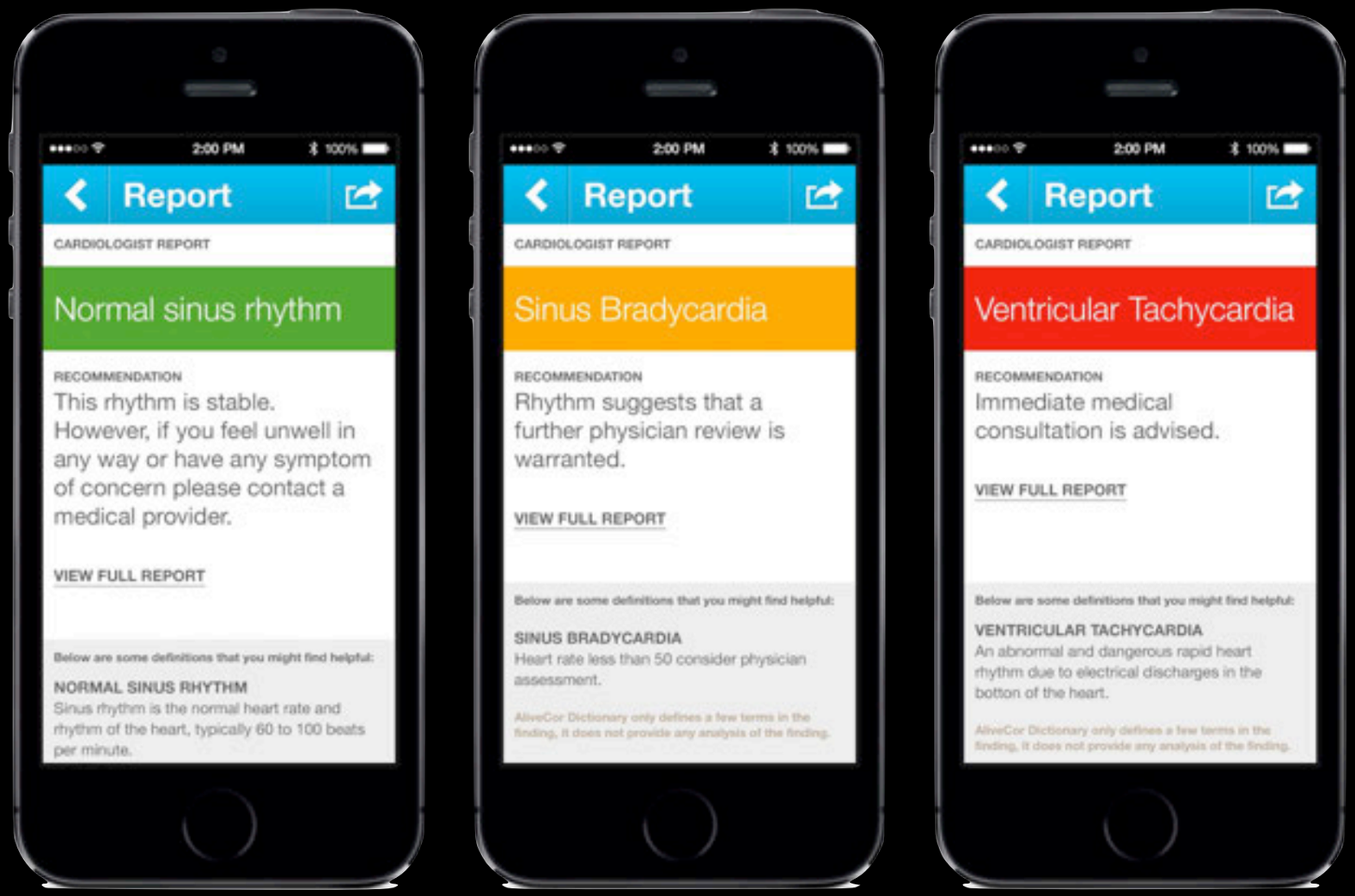
- [ ] Physical activity 운동
- [ ] Medication change 약
- [ ] Coffee 커피
- [ ] Woke up from sleep 기상직후

COMMENTS

측정 시 증상

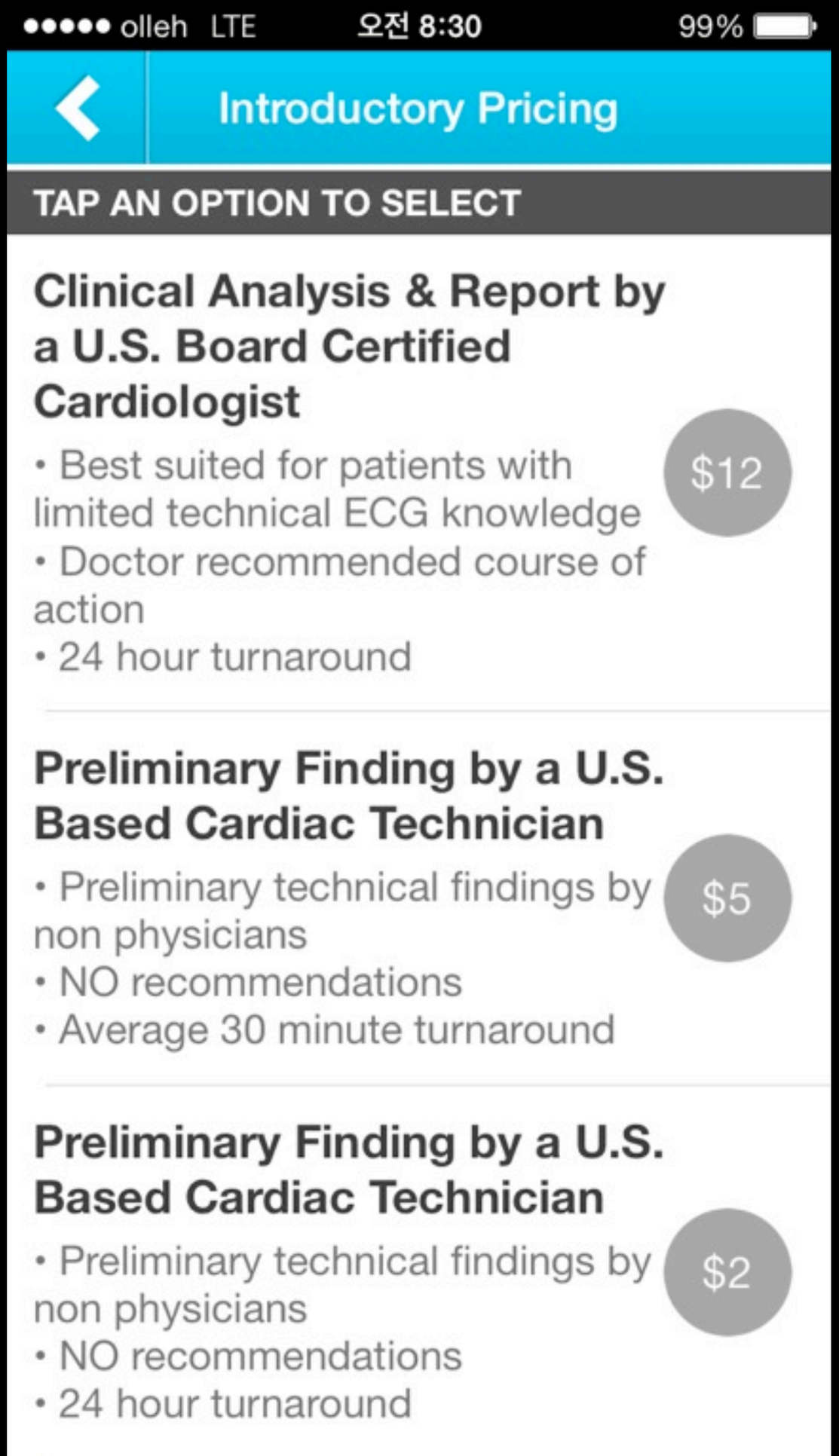
측정 시 활동

AliveInsight, the remote ECG interpretation service



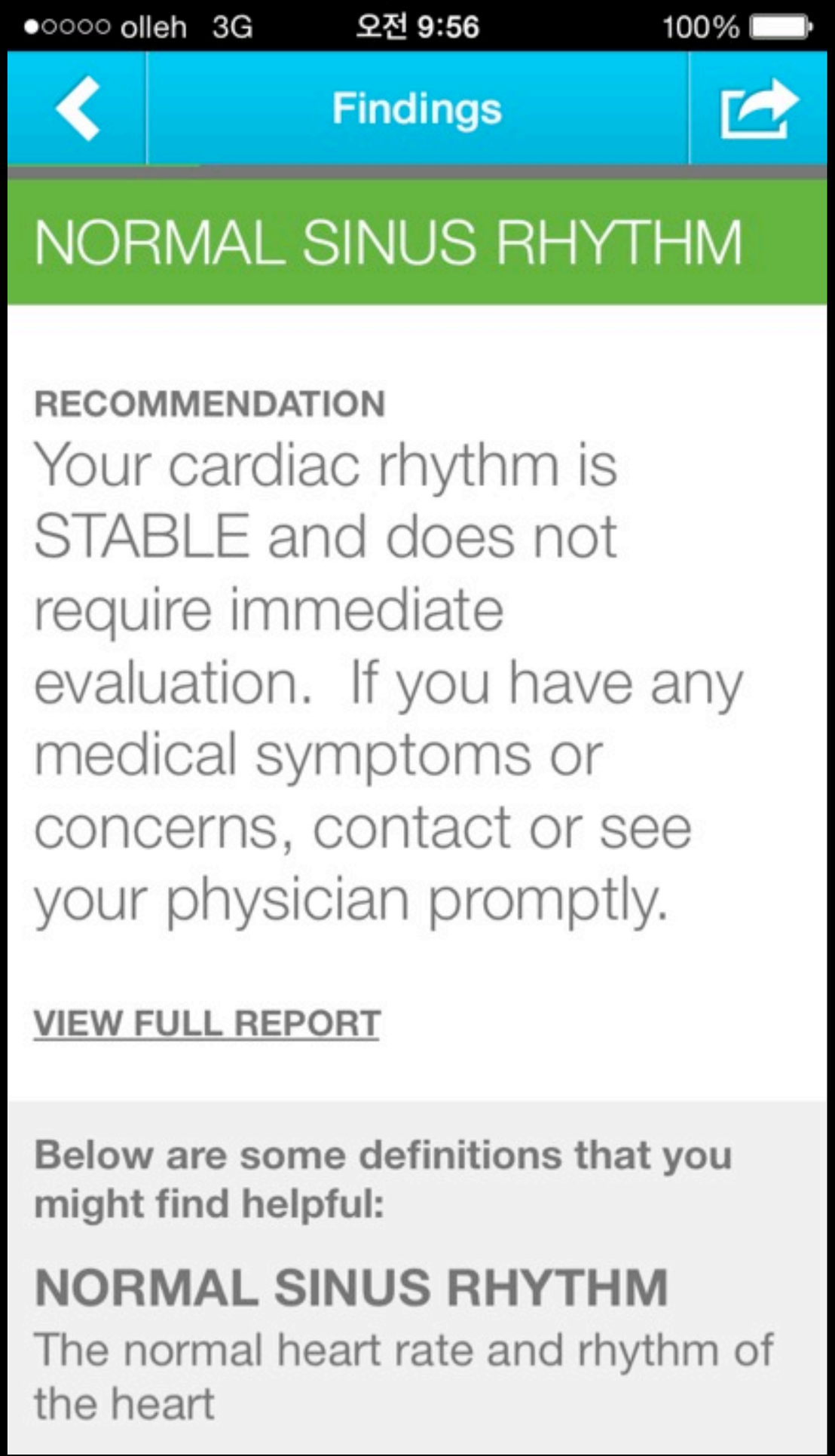
AliveCor AliveInsights will allow patients to send their recorded ECG readings to remote cardiac technicians or cardiologists for interpretation at any time, for a fee.

단순히 정확한 '측정'에만 그치지 않고,
환자에게 실질적인 효용을 제공



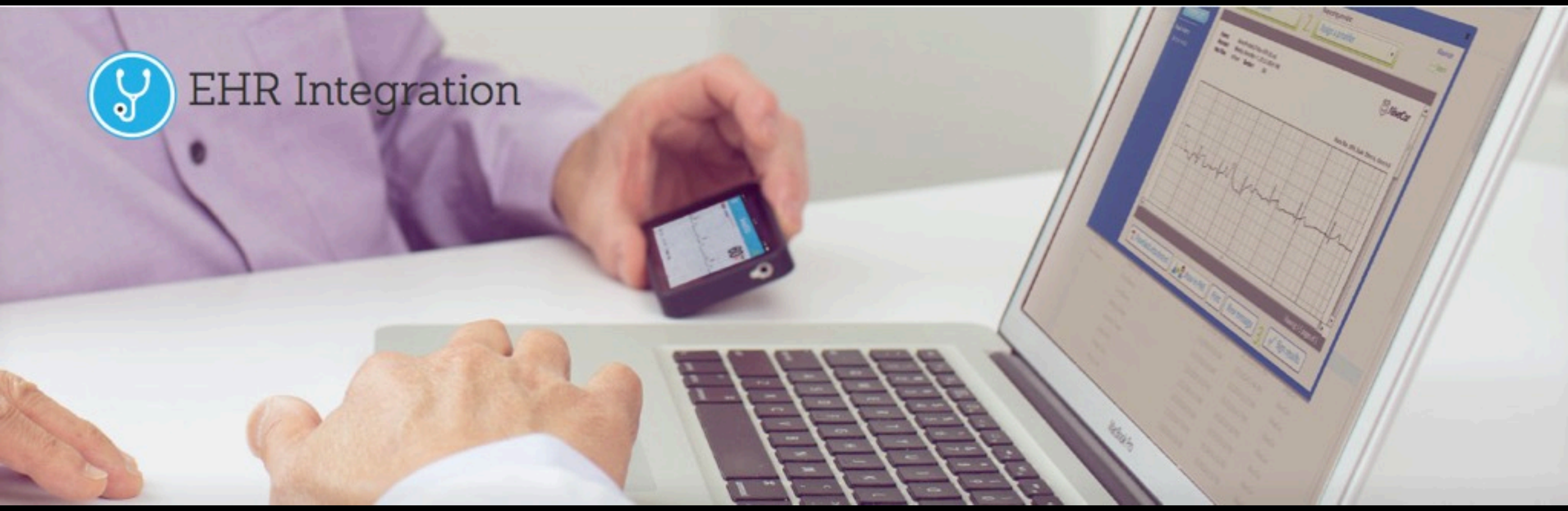
- 미국의 심혈관계 전문의로부터
- 24시간 내에
- 데이터 해석 및 권고 사항 제공
- $12

- 심혈관계 전문가 (전문의는 아님)
- 데이터 해석 + 권고사항 없음
- $5 → 30분 내
- $2 → 24시간 내



"심장박동은 안정적이기 때문에,
당장 병원에 갈 필요는 없겠습니다.
그래도 이상이 있으면 전문의에게
진료를 받아보세요. "

AliveCor Offers Integration With Practice Fusion's Electronic Health Records Platform



- 미국에서 가장 큰 전자의료기록(EMR) 회사인 Practice Fusion과 연동
- 환자들이 평소에 측정한 ECG 데이터가 EMR과 실시간 연동
- 모바일 헬스케어로 측정한 데이터를 의사들이 진료에 활용 가능!

모바일 헬스케어가 주류 의료 시스템과 결합

AliveCor gets FDA clearance for atrial fibrillation algorithm

By: Jonah Comstock | Aug 21, 2014

Tags: AliveCor | AliveCor ECG | atrial fibrillation | mobile health | remote patient monitoring | smartphone ECG |

AliveCor has received an additional FDA 510(k) clearance, this time for an algorithm that allows its smartphone ECG to detect atrial fibrillation — an abnormal heart rhythm that isn't always detectable to the patient, but if left untreated can lead to stroke or congestive heart failure — with high accuracy. The app is set to launch for consumers in September.

"Our pretty strong belief is that if people did this, if they got the app and used it regularly, especially in the at risk population of people over 40, that they will catch atrial fibrillation that was previously undiagnosed, using a mobile technology," Euan Thomson, president and chief executive officer of AliveCor, told MobiHealthNews. "It's got great value to patients. From a conceptual standpoint or from a mobile helath perspective, I think we're really delivering on the promise of mobile health in a very meaningful way."

AliveCor's smartphone ECG, which is available for both Apple and Android phones, has had FDA clearance since last fall and has been in use by patients since March. But up until now, consumers using the device would simply send their ECG readings to a board-certified cardiologist or cardiac technician, who would turn a response around in 24 hours — or faster for a small fee.

With the new algorithm, patients will be able to take the ECG reading and immediately find out if they have atrial fibrillation. Then they can contact a board-certified cardiologist to confirm the result, and finally take the print out to their own physician. Thomson said that the algorithm has a 100 percent sensitivity (it never returns a false negative) and a 97 percent specificity (it returns false positives about 3 percent of the time). For obvious reasons, the algorithm was designed to err on the side of false positives.

There are no plans to eliminate the cardiologists from the equation, but Thomson does think the algorithm will eventually surpass them, since it's continually learning from the ECG readings flooding into AliveCor's database and improving itself.

"AliveCor has received an additional FDA 510(k) clearance, this time for an algorithm that allows its smartphone ECG to detect atrial fibrillation with high accuracy."

"the algorithm has a 100 percent sensitivity (it never returns a false negative) and a 97 percent specificity (it returns false positives about 3 percent of the time). For obvious reasons, the algorithm was designed to err on the side of false positives"

AliveCor, "So What?"

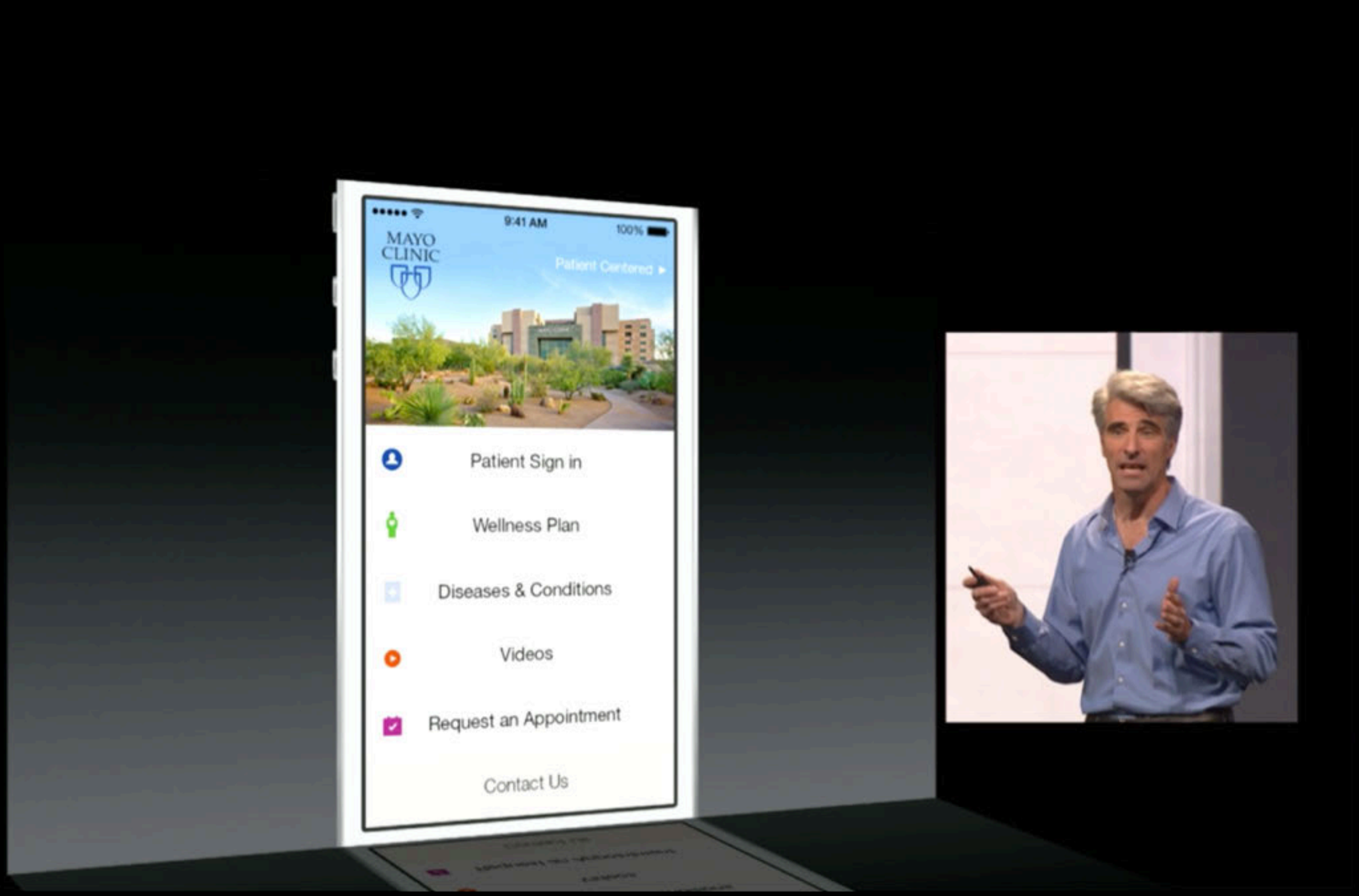
- With measured ECG data,
- 1. We can send it to doctor and get diagnosis.
- 2. The data is integrated into the EHR of hospitals.
- 3. Algorithm automatically diagnose whether we have AF.

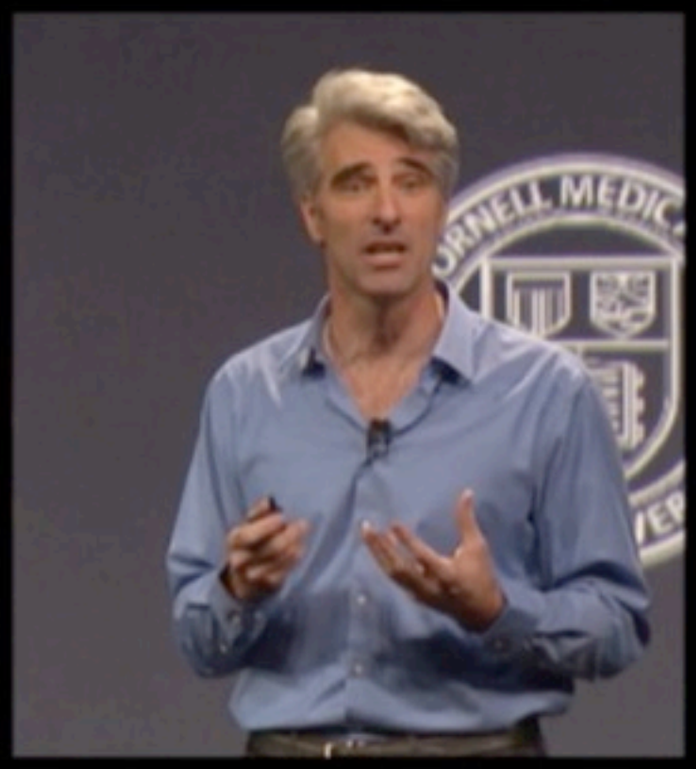
It can provide actual clinical benefits to patients!


9:41 AM
100%
Dashboard
Calories Burned
Daily Avg: 428
467cal
Today
743
136
May 5
12
19
26
June 2
Sleep
Daily Avg: 7h 9m
7h 29m
Last Night
9.5
9:41 AM
100%
Calories Burned
467cal
Today
743
136
12
19
26
June 2
All Data
Data Point

9:41 AM
100%
Wellness Plan
Contact
Blood Pressure
SYSTOLIC
DIASTOLIC
140 / 92 ↑ Elevated
Weight
POUNDS
NEXT GOAL
210 ↑ +2
200
Activity
CALORIE BURN
GOAL
2332
2500
Diet
CALORIES
GOAL
1912
1700

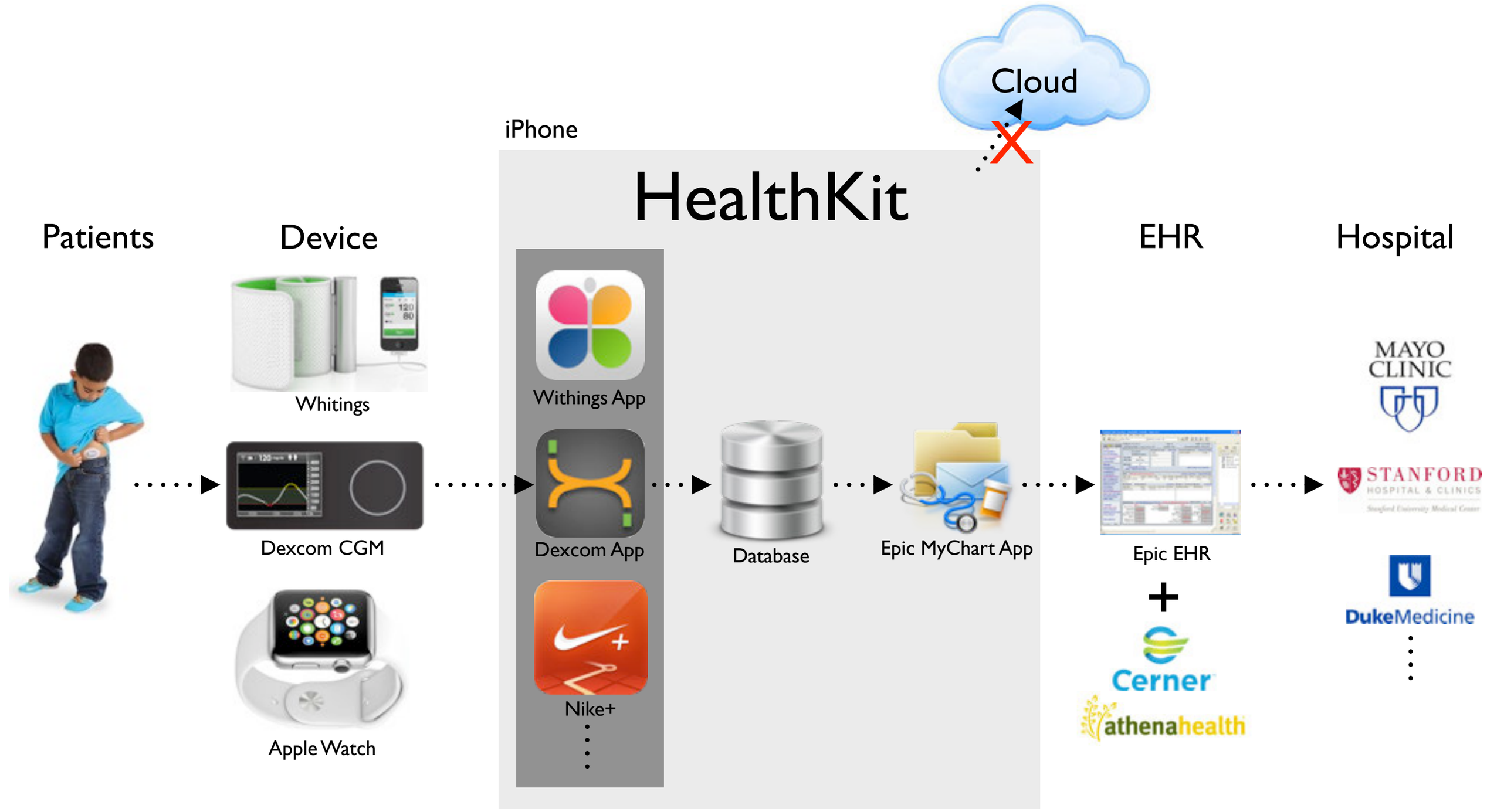

NIKE+ RUNDOWN
MAY 2014
53,567
NIKEFUEL
07
WORKOUTS
SLEEP AVERAGE
7hrs 20min
WEIGHT TARGET
143lbs
NUTRITION BALANCE
80%
Nike+ FuelCoach
32,576
Nike+ Running
11,832
FitStar
6,563


9:41 AM
100%
MAYO CLINIC
Patient Centered
Patient Sign in
Wellness Plan
Diseases & Conditions
Videos
Request an Appointment
Contact Us


Mount Sinai
Cincinnati Children's
Stanford Hospital & Clinics
Penn Medicine
Yale New Haven Health
Cambridge University Hospitals
NHS Foundation Trust
NHS
Oregon Health & Science University
OHSU
University of Iowa Health Care
Texas Health Resources
UCLA Health
Sutter Health
Cleveland Clinic
The Children's Hospital of Philadelphia
BaylorScott&White Health
Reshape Center
Radboudumc
Weill Cornell Medical College
Physician Organization
Johns Hopkins Medicine
Ann & Robert H. Lurie Children's Hospital of Chicago
Cedars-Sinai
Kaiser Permanente
NYU Langone Medical Center
Duke Medicine

Apple HealthKit

- ‘Health’, ‘HealthKit’ platform is included to iOS8.
- 3rd party healthcare devices/application will be integrated into and managed by the ‘HealthKit’ platform.
- Wellness/medical data measured by the devices will sent to hospitals through EHR, providing personal health services.



- Data stored in DB on the iPhone (, not mirroring to the cloud)
- Consumer controls what data goes in/out, privacy level
- HealthKit connects/direct devices, store data based on privacy rules

REUTERS EDITION: U.S.

HOME BUSINESS MARKETS WORLD POLITICS TECH OPINION BREAKINGVIEWS

Exclusive: Apple's health tech takes early lead among top hospitals

BY CHRISTINA FARR

SAN FRANCISCO | Thu Feb 5, 2015 5:10pm EST

A general view of an Apple store in the Manhattan borough of New York September 7, 2014, ahead of the expected release of iPhone 6 and other products this week.

CREDIT: REUTERS/CARLO ALLEGRI

FACTBOX

Hospitals launching pilots of Apple health tech

(Reuters) - Apple Inc's (AAPL.O) healthcare technol
spreading quickly among major U.S. hospitals, show
promise as a way for doctors to monitor patients rem
lower costs.

Fourteen of 23 top hospitals contacted by Reuters said they have rolled out a pi
program of Apple's HealthKit service - which acts as a repository for patient-g

2015.2.5

- 애플 HealthKit 가 미국의 23개 선도병원 중에, 14개의 병원과 협력
- 경쟁 플랫폼 Google Fit, S-Health 보다 현저히 빠른 움직임
- Beth Israel Deaconess 의 CIO
  - "25만명의 환자들 중 상당수가 웨어러블로 각종 데이터 생산 중. 이 모든 디바이스에 인터페이스를 우리 병원은 제공할 수 없다. 하지만 애플이라면 가능하다."

Now, let's talk based on the data.

- Data to show efficacy & validity of digital healthcare technology have begun to be generated.
- Most of the data generated during last 6 months.
- And probably this is just the beginning…

Now, let's talk based on the data.

- IBM Watson
  - 200 cases of leukemia
  - Overall Accuracy 82.6%, False positive 2.9%, False negative 0.4%
- Google Glass (Augemedix)
  - Over 2,700 patient visits
  - Direct Patients Care: 35% → 70%, In EHR: 53% → 15%
- Ingestible Sensor (Proteus Digital Health)
  - 412 patients, 20,933 uptakes, 5,656 days
  - Accuracy 99.1%, False positive rate 0%
- AliveCor AF diagnosis
  - 100% sensitivity, 97% specificity

More data will be generated soon

- Google Glass (Pristine): feasibility study of dermatology consultation in ER
- Apple HealthKit : pilot studies initiated in Stanford and Duke
- Tricorder X-PRIZE: clinical study started in spring 2015

- Personal Genome Service
  - 23andMe
- Diagnosis by Computers
  - IBM Watson
- Wearable Healthcare Devices
  - Google Glass
  - Proteus Digital Health
- 3D Printers
- Smart/Mobile Healthcare
  - AliveCor
  - Apple HealthKit

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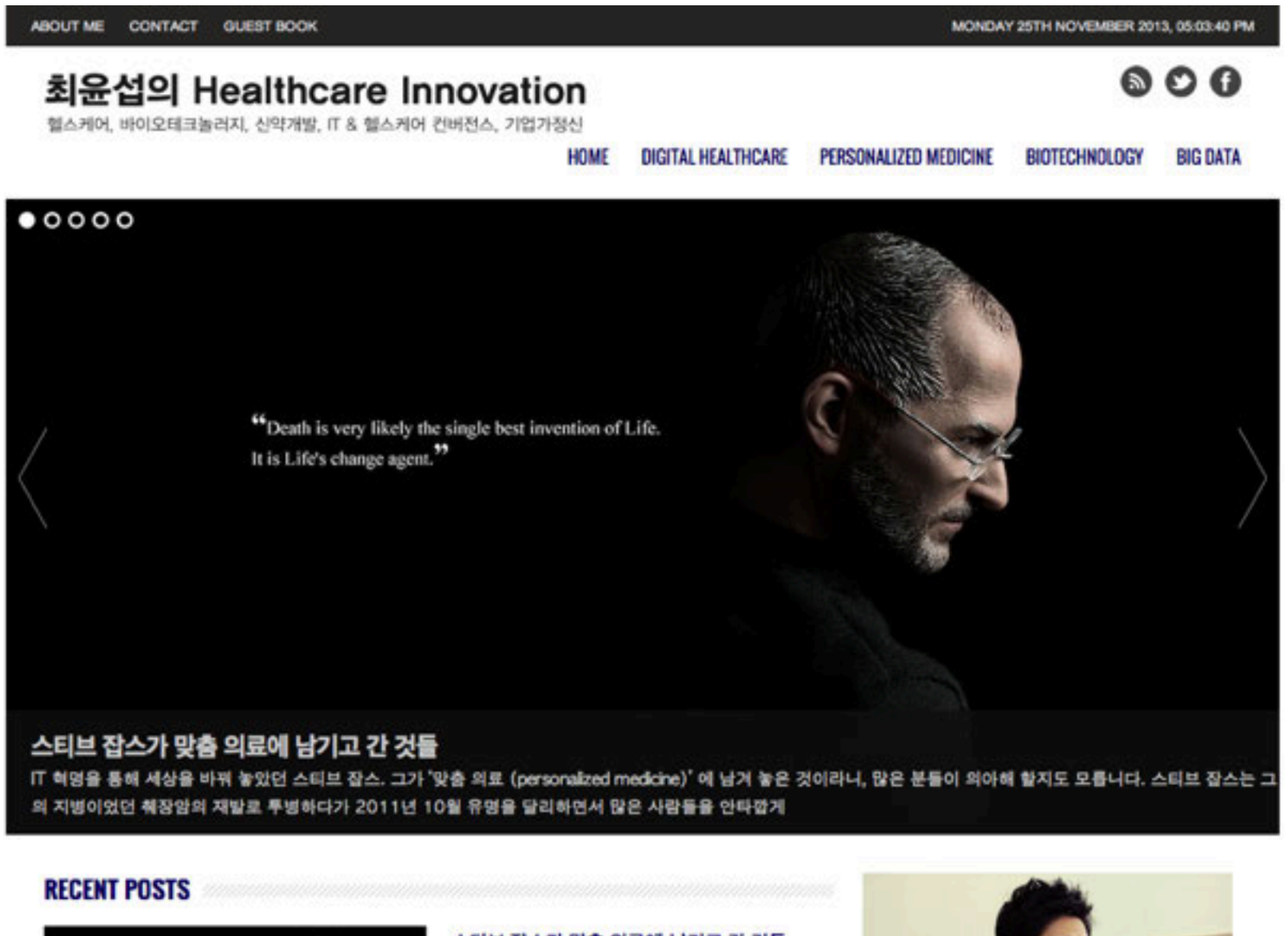
- 페이스북: Yoon Sup Choi



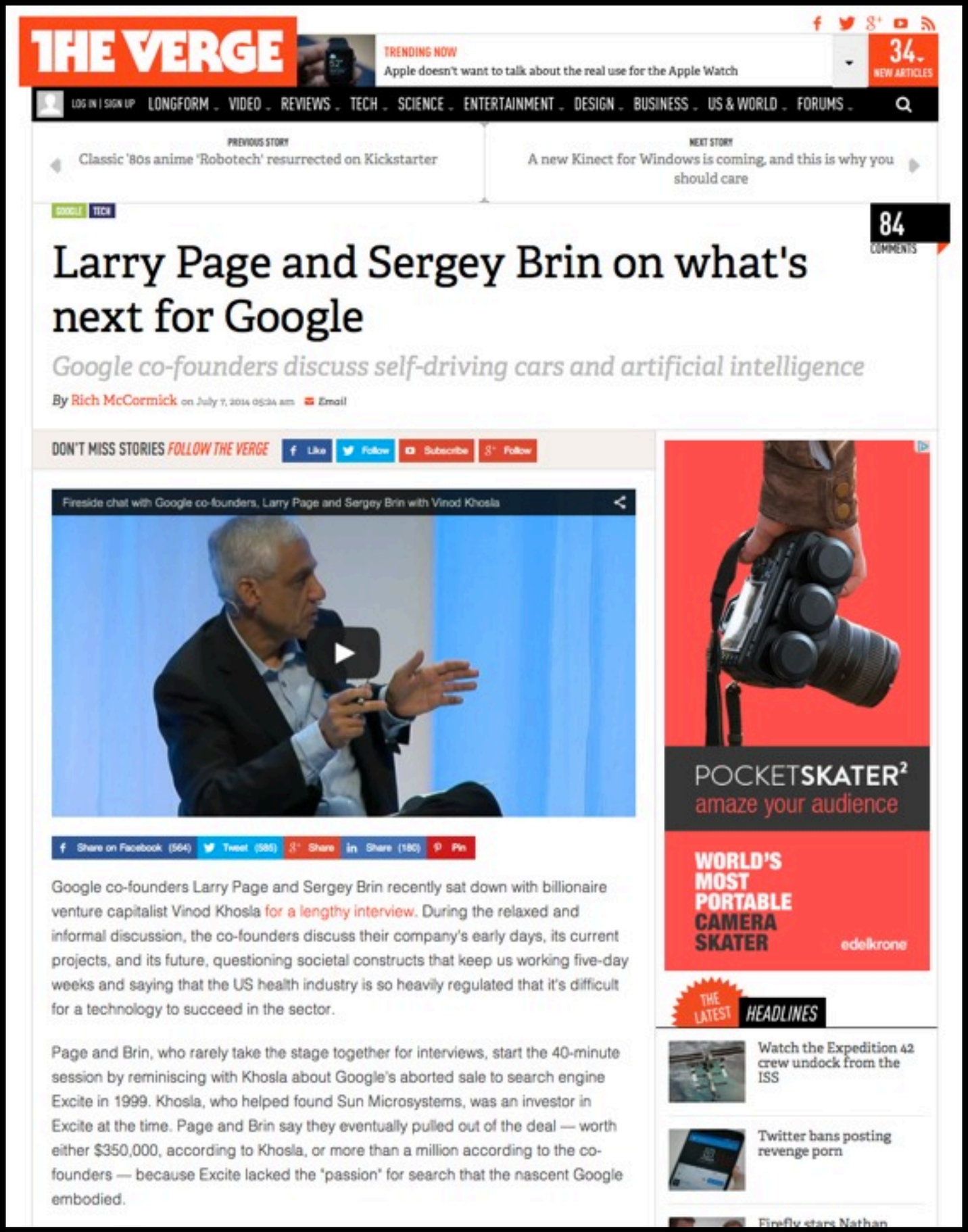
Healthcare Innovation

이 미 시 작 된 미 래
헬스케어 이노베이션

최 윤 섭 지 음

클라우드나인
CLOUD 9

FDA의 디지털 헬스 규제 완화 기조



"Generally, health is just so heavily regulated. It's just a painful business to be in. It's just not necessarily how I want to spend my time. Even though we do have some health projects, and we'll be doing that to a certain extent. But I think the regulatory burden in the U.S. is so high that think it would dissuade a lot of entrepreneurs."

Sergey Brin, July 2014

FDA finalizes plans to deregulate MDDS health software

By: Brian Dolan | Feb 9, 2015

Tags: digital health regulation | FDA draft guidance | FDA final guidance | FDA MMA | FDA regulated mobile medical apps | MDDS | medical device software | mobile health regulation |


FDA's Bakul Patel

Last June in a draft guidance document, the FDA proposed to further de-regulate a specific type of health software, which included a number of mobile medical apps and telehealth platforms, from FDA-registered Class 1 devices to an unregulated status. Last week the FDA moved to finalize that guidance, building on a spate of recent guidances that both make clear where regulatory lines for health software already exist and move some healthtech categories into unregulated territory.

The most recent final guidance specifically relates to MDDS software, which the FDA deregulated from Class 2 to Class 1 in 2011. MDDS are systems designed and marketed to transfer, store, convert according to preset specifications, or display medical device data without controlling or altering the function or parameters of any connected medical device.

Examples of health software platforms that have class 1 medical device clearance as an MDDS include Validic's healthcare data integration platform and Qualcomm's 2net platform for home health data. Another digital health product, Glooko's MeterSync cable and companion logbook app originally started out as a class I MDDS device, but the company added additional functionality that bumped it up to a class II 510(k) clearance, which allowed it to begin offering more analysis of the collected health data.

"Now FDA has exempted the software from all FDA regulation, and indeed swept in image management software," Epstein Becker's Brad Thompson told MobiHealthNews in an email. "The implications are profound, both for MDDS type software, but also for what it suggests about the future for health information technology generally. FDA is quite earnestly working to ensure that it uses the lightest regulatory touch appropriate for software."

When the FDA first proposed this further deregulation of MDDS software, FDA senior policy advisor Bakul Patel penned a blog post to explain the move:

"Why would we do that?" he wrote at the time. "Since our 2011 action, we've been working with two other federal agencies that oversee health IT – The Office of the National Coordinator for Health IT (ONC) and the Department of Health and Human Services, and the Federal Communications Commission (FCC) on a proposed risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. In the course of our work on the proposed framework, we sought extensive public feedback. And we listened."

Given the MDDS definition above, it's clear that this group is related to the medical device accessory category, especially for mobile medical apps. FDA's recent draft guidance on accessory devices is, therefore, relevant. The FDA seems to agree as it is hosting a webinar later this month to discuss the MDDS final guidance, the accessory draft guidance, and the general wellness draft guidance.

Soon after Apple announced its HealthKit offering the FDA added a new kind of mobile medical app that it said it would not regulate as a medical device. The FDA's description squared with Apple's plans for HealthKit, and also read like a specific example of an MDDS:

"Mobile apps that allows a user to collect, log, track and trend data such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a heath care provider, or upload it to an online (cloud) database, personal or electronic health record. [Added June 11, 2014]."

- 2015년 들어, FDA가 디지털 헬스 분야의 규제를 완화하는 행보들을 보이고 있음
- "혁신적 기술의 산업화에 걸림돌이 되지 않겠다"를 실천으로 옮기고 있음

FDA의 디지털 헬스 규제 완화 움직임

- 모바일 헬스 (웰니스/의료기기 구분) 신규 가이드라인 제시 (2015.1.20)
- 모바일 의료기기 액세서리에 관한 신규 가이드라인 제시 (2015. 1. 20)
- MDDS 헬스 소프트웨어에 대한 규제 철폐 (2015. 2. 9)
- 23andMe 의 DTC 유전자 테스트 최초 승인 (2015.2.19)

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